Records processed under FOIA Request #2015-6024 Released by CDRH on 09-26-2016.

K131482

NOV 2 2 2013

| 510(k) Summary | |
|---|---|
| **Trade Name:** | SOFIA™ Distal Access Catheter |
| **Generic Name:** | Percutaneous Catheter |
| **Classification:** | Class II, 21 CFR 870.1250 (DQY), 21 CFR 870.1200 (DQO) |
| **Submitted By:** | MicroVention, Inc<br>1311 Valencia Avenue<br>Tustin, California U.S.A. |
| **Contact:** | Naomi Gong |
| **Date:** | 2013 November 13 |
| **Predicate Device:** | Chaperon Guiding Catheter (K082385)<br>Headway Duo Microcatheter (K120917) |

## Device Description:

The SOFIA Distal Access Catheter is a single-lumen, flexible catheter designed with coil and braid reinforcement. The distal segment is steam-shapeable and it has a hydrophilic coating for navigation through the vasculature. The radiopaque marker is located at the distal end of the catheter for visualization under fluoroscopy. An introducer sheath and shaping mandrel are also provided.

## Indications For Use:

The SOFIA Distal Access Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate introduction of diagnostic or therapeutic devices. It is not intended for use in coronary arteries.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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## Technological Comparison:

| | Chaperon Guiding Catheter | SOFIA Distal Access Catheter | Headway Duo Microcatheter |
|---|---|---|---|
| Intended Use | Intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries. | Intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries. | Intended for general intravascular use, including the peripheral and coronary vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as embolization materials. Intended for neurovascular use for the infusion of diagnostic agents, such as contrast media, and therapeutic agents that have been cleared or approved for use in the neurovasculature and are compatible with the inner diameter of the microcatheter. |
| Material | | | |
| Catheter Body | Outer layer of polyester elastomer; stainless steel braid; inner layer of PTFE (polytetrafluoroehthylene). | Outer layer of polyurethane elastomer (Polyblend and Pellethane), polyether block amide (Pebax) and polyamide (Grilamid); inner layer of stainless steel braid/coil, PTFE and polyolefin elastomer | Outer layer of polyether block amide (Pebax) and polyamide (Grilamid); inner layer of stainless steel braid/coil and PTFE |
| Marker | Tungsten | Platinum/Iridium | Platinum/Iridium |
| Hub | Nylon | Nylon | Nylon |
| Strain Relief | Polyester elastomer | Polyurethane | Pebax |
| Introducer | Not applicable | Pebax | Pebax |
| Shaping Mandrel | Not applicable | Stainless steel | Stainless steel |



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| | Chaperon Guiding Catheter | SOFIA Distal Access Catheter | Headway Duo Microcatheter |
|---|---|---|---|
| Catheter size | 5 F (outer catheter) | 5 F | 1.6 - 2.1 F |
| ID | 0.059 inch (1.5 mm) | 0.055 inch (1.4 mm) | 0.0165 inch (0.42 mm) |
| OD | 0.068 inch (1.7 mm) | 0.068 inch (1.7 mm) | 0.023 – 0.0275 inch (0.58 – 0.70 mm) |
| Effective Length | 95 cm (outer)<br>117 cm (inner) | 125 cm | 157 and 168 cm |
| Coating | Hydrophilic coating (Terumo proprietary coating) | Hydrophilic coating (Hydak® – same) | Hydrophilic coating (Hydak® – same) |
| Tip Configuration | Preshaped | Steam shapeable by user | Steam shapeable by user |
| Guidewire Compatibility | 0.035 inch or 0.038 inch | 0.035 inch or 0.038 inch | 0.014 inch or smaller |
| Accessories | N/A | Introducer sheath and shaping mandrel | Introducer sheath and shaping mandrel |
| Method of Supply | Sterile and single use | Sterile and single use | Sterile and single use |
| Sterilization Method | Ethylene Oxide | Ethylene Oxide | Ethylene Oxide |
| Packaging Configuration | Catheter placed on packaging card that is inserted into Tyvek® pouch. Pouch and IFU placed in bleached sulfate carton box. | Catheter placed into a HDPE dispenser tube. Dispenser tube, introducer and shaping mandrel placed on a polyethylene packaging card that is inserted into a Tyvek® pouch. Pouch and IFU placed in bleached sulfate carton box. | Catheter placed into a polyethylene dispenser hoop. Introducer and shaping mandrel placed on polyethylene packaging card. Dispenser hoop and packaging card inserted into Tyvek® pouch. Pouch and IFU placed in bleached sulfate carton box. |



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## Verification and Test Summary:

| **Bench Testing** | | |
|---|---|---|
| **Test** | **Results** | **Conclusions** |
| Simulated Use | Test articles achieved a rating $\geq 3$ for preparation/ease of assembly, introducer sheath interaction, introducer peel away, tracking with guidewire/microcatheter, microcatheter/guidewire lockup, lubricity and durability of hydrophilic coating, microcatheter/ guidewire removal, removal/ aspiration of clot, mechanical clot retriever and stent delivery with no particles | Device performs as intended under simulated use conditions |
| Equipment Interface | Test articles compatible with 0.035-inch and 0.038-inch guidewires, 6F or larger guide catheter/guiding sheath, common RHVs using insertion tool, stopcocks and $\leq 0.027$-inch microcatheters | Device compatible with recommended accessories commonly used in intravascular procedures |
| Dimensional and Physical Attributes | Test articles met the specified dimensional requirements for catheter OD, catheter ID, overall working length, length of distal section, length of distal tip to marker band and total length of hub/strain relief | Device met established dimensional and physical specifications |
| Kink Resistance | No kinks at 1 cm, 4 cm, 12 cm and 25 cm from distal tip when wrapped around 0.025-inch and 0.030-inch pin gauges<br><br>No kinks noted during simulated use testing | Device resistant to kinking around small radii turns |
| Tip Shapeability | Tip angle of test article equivalent to competitive devices after steam shaping using mandrel with an angle of approximately $90^{\circ}$ | Shapeability of distal tip after steam shaping equivalent to competitive devices |
| Radio Detectability | Distal marker band visible under fluoroscopy | Device radiopacity equivalent to or better than predicate and competitive devices |



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| **Bench Testing** | | |
|---|---|---|
| **Test** | **Results** | **Conclusions** |
| Gauging (ISO 594-2) | Gauging pin and hub align in limit planes | Device hub meets the requirements of ISO 594-2 |
| Separation Force (ISO 594-2) | Mating parts separation force greater than 25 N | Device hub meets the requirements of ISO 594-2 |
| Unscrewing Torque (ISO 594-2) | Test article luer remains attached after applying an unscrewing torque not less than 0.02 Nm for a minimum of 10 seconds | Device hub meets the requirements of ISO 594-2 |
| Stress Cracking (ISO 594-2) | No stress cracks on test article hub | Device hub meets the requirements of ISO 594-2 |
| Ease of Assembly (ISO 594-2) | Components fit together securely with no resistance observed between test article luer and reference fitting | Device hub meets the requirements of ISO 594-2 |
| Resistance to Overriding (ISO 594-2) | Test article luer does not override reference fitting threads | Device hub meets the requirements of ISO 594-2 |
| Durability/Lubricity of Hydrophilic Coating | Test article achieved a rating of $\geq 3$ during simulated use testing for coating durability and lubricity. | Device tracks easily with no coating cracking or separation |
| Catheter Stiffness | Device stiffness equivalent to predicate and competitive devices | Device tracks in tortuous anatomy while advancing to target site |
| Torque Strength | No catheter breakage after 50 rotations | Device torque strength same as predicate device |
| Catheter Flexural Fatigue | No flexural fatigue following repeated bending during simulated use testing and repeated hoop stress following pressure and air aspiration testing | Device integrity suitable for intended clinical use |
| Surface Contamination | Test article free from surface contaminants from uncured coating surface particulates > 0.02 $mm^2$, embedded particulates<br><br>Distal tip smooth and tapered<br><br>PTFE inner layer not delaminated | Device integrity suitable for intended clinical use |
| Force at Break (Distal and Hub) | Catheter force at break $\geq$2.25lbf for distal section and hub/catheter junction | Tensile strength test results equivalent to predicate and competitive devices |



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| **Bench Testing** | | |
|---|---|---|
| **Test** | **Results** | **Conclusions** |
| Flow Rate | Flow rate at 100 psi and 300 psi with diagnostic agents (e.g., saline, contrast media) equivalent to or better than competitive devices | Device meets specified requirements for delivery of diagnostic agents |
| Static Burst Pressure | No damage of pressurized catheter at 46 psi | Device integrity suitable for intended clinical use and met requirements of ISO 10555-1 |
| Fluid Leakage at > 46 psi | No liquid leakage from hub and catheter shaft at 46 psi for 30 seconds | Device integrity suitable for intended clinical use and met requirements of ISO 10555-1 |
| Air Leakage | No air leakage at hub into syringe for 15 seconds | Device integrity suitable for intended clinical use and met requirements of ISO 10555-1 |
| Dynamic Burst | Test articles did not burst at or below 300 psi | Device met labeled maximum infusion pressure of 300 psi |
| Particulate Test | Less than 25 particles greater than 10 microns per ml volume and less than 3 particles less than 25 microns per ml volume<br><br>No particles greater than 70 microns | Device met specifications for maximum allowable particles |

| **Biocompatibility** | | |
|---|---|---|
| **Test** | **Results** | **Conclusions** |
| Cytotoxicity – MEM Elution Assay (ISO 10993-5) | Cell culture treated with test article exhibited slight reactivity (Grade 1) | Non-cytotoxic |
| Sensitization/Irritation – Kligman Maximization Test (ISO 10993-10) | Extracts of the test article elicited no reaction at the challenge (0% sensitization) following the induction phase (Grade 1). | Weak allergic potential or sensitizing capacity |
| Sensitization/Irritation – Intracutaneous Injection Test (ISO 10993-10) | Extracts of the test article did not show a significantly greater biological reaction than the sites injected with the control article | Non-irritant |
| Hemocompatibility – Rabbit Blood Direct and Indirect Contact (ISO 10993-4) | The hemolysis index was 0.13% (direct contact) and 0.0% (indirect contact) | Non-hemolytic |



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| **Biocompatibility** | | |
|---|---|---|
| **Test** | **Results** | **Conclusions** |
| Hemocompatibility – Unactivated Partial Thromboplastin Time Assay Direct Contact (ISO 10993-4) | No statistically significant difference found between the Unactivated Partial Thromboplastin Time (UPTT) of the plasma exposed to the test article and that of the plasma exposed to either the negative control or the untreated control | No effect on coagulation |
| Hemocompatibility – Complement Activation Assay (ISO 10993-4) | C3a and SC5b-9 levels ≤ negative and untreated controls | No effect on complement activation |
| Hemocompatibility – Thrombogenicity Study in Dogs (ISO 10993-4) | Minimal thrombosis observed with a Grade 0 in two out of two test sites and two out of two control sites | No significant thrombosis |
| Systemic Toxicity – Systemic Injection Test (ISO 10993-11) | Extracts of test article did not induce a significantly greater biological reaction than the control extracts when injected in Swiss Albino mice | No toxic effects |
| Systemic Toxicity - Rabbit Pyrogen Test (ISO 10993-11) | The temperature increases (maximum) was 0.03°C from baseline | Non-pyrogenic |

## Summary of Substantial Equivalence:

The data presented in this submission demonstrates the technological similarity and equivalency of the SOFIA Distal Access Catheter when compared with the predicate Chaperon Guiding Catheter (K082385) and the HEADWAY DUO Microcatheter (K120917) devices. The devices:

- Have an equivalent intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Are packaged and sterilized using the same methods.

In summary, the SOFIA Distal Access Catheter described in this submission is substantially equivalent to the predicate devices.



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 22, 2013

Micro Vention, Inc.
c/o Ms. Naomi Gong
Sr. Regulatory Affairs Project Manager
1311 Valencia Avenue
Tustin, CA 92780

Re: K131482
Trade/Device Name: SOFIA Distal Access Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, DQO
Dated: October 22, 2013
Received: October 23, 2013

Dear Ms. Gong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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# Indications for Use

510(k) Number (if known): K131482

Device Name: SOFIA Distal Access Catheter

Indications For Use:

*The SOFIA Distal Access Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries.*

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Food and Drug Administration
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Silver Spring, MD 20993-0002

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c/o Ms. Naomi Gong
Sr. Regulatory Affairs Project Manager
1311 Valencia Avenue
Tustin, CA 92780

Re: K131482
Trade/Device Name: SOFIA Distal Access Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, DQO
Dated: October 22, 2013
Received: October 23, 2013

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Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
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Enclosure

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**Concurrence & Template History Page**
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K131482/S002

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

| Digital Signature Concurrence Table | |
|---|---|
| Reviewer Sign-Off | Samuel K. Shimp III<br>11/13/2013 @ 3:08PM |
| Branch Chief Sign-Off | Quynh Hoang<br>November 21, 2013<br>DNPMD/NNDB |
| Division Sign-Off | Joyce M. Whang -S<br>2013.11.22 12:18:11 -05'00' |

Template Name: K1(A) – SE after 1996

Template History:

| Date of Update | By | Description of Update |
|---|---|---|
| 7/27/09 | Brandi Stuart | Added Updates to Boiler Table |
| 8/7/09 | Brandi Stuart | Updated HFZ Table |
| 1/11/10 | Diane Garcia | Liability/Warranty sentence added at bottom of 1st page |
| 10/4/11 | M. McCabe Janicki | Removed IFU sheet and placed in Forms |
| 9/25/12 | Edwena Jones | Added digital signature format |
| 12/12/12 | M. McCabe Janicki | Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002". |
| 4/2/2013 | M. McCabe Janicki | Edited sentence that starts "If you desire specific advice for your device on our labeling regulation (21 CFR Part 801)..." Replaced broken Compliance link with general link to DSMICA. |
| 4/12/2013 | Margaret McCabe Janicki | Fixed a typo: Paragraph 1, final sentence, "We remind you, however; that device labeling must be truthful..." Replaced incorrect semicolon with a comma. |

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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# Indications for Use

510(k) Number (if known): K131482

Device Name: SOFIA Distal Access Catheter

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S



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4

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K131489

FDA CDRH DMC
MAY 23 2013
Received

MicroVention® TERUMO

U.S. Food and Drug Administration
Center for Devices and Radiologic Health
Document Mail Center **(WO66-G609)**
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

May 21, 2013

| | | |
|---|---|---|
| RE: | **Special 510(k) Notification:** | SOFIA Distal Access Catheter |
| | **Predicate device:** | Chaperon Guiding Catheter (K082385) |
| | **Classification:** | II |
| | **Regulation Number:** | 21 CFR 870.1250 |
| | **Product Code:** | DQY |
| | **Classification Committee:** | Cardiovascular |

Dear Sir/Madam:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act as amended by the Medical Device Amendment of 1976, MicroVention, Inc. hereby submits this Special Premarket Notification 510(k) for the SOFIA Distal Access Catheter. The SOFIA is a single lumen catheter designed to be introduced over a steerable guidewire to access the vasculature. The device has been designed, developed and tested according to the FDA special control guidance document: Short-Term and Long-Term Intravascular Catheter and the ISO 10555-1.

The SOFIA Distal Access Catheter utilizes the same fundamental scientific technology, basic design, operating principle and intended use as the predicate device, Chaperon Guiding Catheter (K082385). We believe the documentation included in this 510(k) submission supports our conclusion that it is substantially equivalent to the predicate devices.

An eCopy can be found on the included CD and it is an exact duplicate of the paper copy.

**Statement of Confidentiality:** MicroVention, Inc. considers the information in this submission to be confidential commercial information. We have not, to our knowledge, released this information through advertising or any other manner to anyone outside the employ of MicroVention, Inc. We ask that this notification and proprietary information herein be treated as confidential in accordance with the Freedom of Information Act.

Thank you in advance for your consideration of our application. If there are any questions, please contact me at (714) 247-8055 or (949) 282-3742

Naomi Gong
Sr. Regulatory Affairs Project Manager
Tel: (714) 247-8055 or (949) 282-3742
Fax: (714) 247-8014
naomi.gong@microvention.com


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.


35

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MicroVention TERUMO

U.S. Food and Drug Administration
Center for Devices and Radiologic Health
Document Mail Center **(WO66-G609)**
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

May 21, 2013

RE:

| | |
|---|---|
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An eCopy can be found on the included CD and it is an exact duplicate of the paper copy.

**Statement of Confidentiality:** MicroVention, Inc. considers the information in this submission to be confidential commercial information. We have not, to our knowledge, released this information through advertising or any other manner to anyone outside the employ of MicroVention, Inc. We ask that this notification and proprietary information herein be treated as confidential in accordance with the Freedom of Information Act.

Thank you in advance for your consideration of our application. If there are any questions, please contact me at (714) 247-8055 or (949) 282-3742

Naomi Gong
Sr. Regulatory Affairs Project Manager
Tel: (714) 247-8055 or (949) 282-3742
Fax: (714) 247-8014
naomi.gong@microvention.com



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.


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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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# 1. FDA Forms

## 1.1. Medical Device User Fee Cover Sheet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

Form Approved: OMB No. 0910-511 Expiration Date: February 28, 2013. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
**MEDICAL DEVICE USER FEE COVER SHEET**

PAYMENT IDENTIFICATION NUMBER: (b) (4)
Write the Payment Identification number on

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

MICRO VENTION INC
1311 Valencia Avenue
Tustin CA 92780
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****3774

2. CONTACT NAME
Vin Cutarelli

2.1 E-MAIL ADDRESS
vin.cutarelli@microvention.com

2.2 TELEPHONE NUMBER (include Area code)
714-247-8181

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
714-247-8014

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b) (4) 12-Dec-2012

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.


## 1.2. CDRH Submission Coversheet FDA 3514

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records Processed Under FDA Request #2015-6024; Released by CDRH on 09-26-2016.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

# CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

| Date of Submission | User Fee Payment ID Number | FDA Submission Document Number *(if known)* |
|---|---|---|
| 05/21/2013 | (b) (4) | |

## SECTION A TYPE OF SUBMISSION

| PMA | PMA & HDE Supplement | PDP | 510(k) | Request for Feedback |
|---|---|---|---|---|
| ☐ Original Submission | ☐ Regular (180 day) | ☐ Original PDP | ☒ Original Submission: | ☐ Pre-Submission |
| ☐ Premarket Report | ☐ Special | ☐ Notice of Completion | ☐ Traditional | ☐ Informational Meeting |
| ☐ Modular Submission | ☐ Panel Track (PMA Only) | ☐ Amendment to PDP | ☒ Special | ☐ Submision Issue Meeting |
| ☐ Amendment | ☐ 30-day Supplement | | ☐ Abbreviated (Complete section I, Page 5) | ☐ Day 100 Meeting |
| ☐ Report | ☐ 30-day Notice | | ☐ Additional Information | ☐ Agreement Meeting |
| ☐ Report Amendment | ☐ 135-day Supplement | | ☐ Third Party | ☐ Determination Meeting |
| ☐ Licensing Agreement | ☐ Real-time Review | | | ☐ Study Risk Determination |
| | ☐ Amendment to PMA & HDE Supplement | | | ☐ Other *(specify):* |
| | ☐ Other | | | |

| IDE | Humanitarian Device Exemption (HDE) | Class II Exemption Petition | Evaluation of Automatic Class III Designation (De Novo) | Other Submission |
|---|---|---|---|---|
| ☐ Original Submission | ☐ Original Submission | ☐ Original Submission | ☐ Original Submission | ☐ 513(g) |
| ☐ Amendment | ☐ Amendment | ☐ Additional Information | ☐ Additional Information | ☐ Other *(describe submission):* |
| ☐ Supplement | ☐ Supplement | | | |
| | ☐ Report | | | |
| | ☐ Report Amendment | | | |

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

## SECTION B SUBMITTER, APPLICANT OR SPONSOR

| Company / Institution Name | Establishment Registration Number *(if known)* | | |
|---|---|---|---|
| MicroVention, Inc. | 2032493 | | |
| Division Name *(if applicable)* | Phone Number *(including area code)* | | |
| | 714-247-8055 | | |
| Street Address | FAX Number *(including area code)* | | |
| 1311 Valencia Avenue | 714-247-8014 | | |
| City | State / Province | ZIP/Postal Code | Country |
| Tustin | CA | 92780 | USA |
| Contact Name | | | |
| Naomi Gong | | | |
| Contact Title | Contact E-mail Address | | |
| Sr. Regulatory Affairs Project Manager | naomi.gong@microvention.com | | |

## SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

| Company / Institution Name | | | |
|---|---|---|---|
| | | | |
| Division Name *(if applicable)* | Phone Number *(including area code)* | | |
| | | | |
| Street Address | FAX Number *(including area code)* | | |
| | | | |
| City | State / Province | ZIP Code | Country |
| | | | |
| Contact Name | | | |
| | | | |
| Contact Title | Contact E-mail Address | | |
| | | | |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118
Confidential
Page 7 of 334
FSC Publishing Services (301) 443-6740 EF

## SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

☐ Other Reason *(specify):*

## SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

☐ Other Reason *(specify):*

## SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

☒ Other Reason *(specify):*

Catheter is similar to predicate device with same intended use (indications for use)

## SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 1 | DQY | 2 | | 3 | | 4 | |
| 5 | | 6 | | 7 | | 8 | |

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

| | *510(k) Number* | | *Trade or Proprietary or Model Name* | | *Manufacturer* |
|---|---|---|---|---|---|
| 1 | K082385 | 1 | Chaperon Guiding Catheter | 1 | MicroVention, Inc.<br>1311 Valencia Avenue, Tustin, CA 92780 |
| 2 | | 2 | | 2 | |
| 3 | | 3 | | 3 | |
| 4 | | 4 | | 4 | |
| 5 | | 5 | | 5 | |
| 6 | | 6 | | 6 | |

## SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Percutaneous catheter

| | Trade or Proprietary or Model Name for This Device | | Model Number |
|---|---|---|---|
| 1 | SOFIA Distal Access Catheter | 1 | DA5125ST |
| 2 | | 2 | |
| 3 | | 3 | |
| 4 | | 4 | |
| 5 | | 5 | |

FDA document numbers of all prior related submissions *(regardless of outcome)*

| | | | | | |
|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 |
| 7 | 8 | 9 | 10 | 11 | 12 |

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

## SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

| Product Code | C.F.R. Section *(if applicable)* | Device Class |
|---|---|---|
| DQY | 21 CFR 870.1250 | ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified |

Classification Panel

Cardiovascular Devices

Indications *(from labeling)*

The SOFIA Distal Access Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries.

Records processed under FOIA Request #2015-6024, Released by CDRH on 09-26-2016.

| | |
|---|---|
| ***Note:*** Submission of the information entered in Section H does not affect the need to submit device establishment registration. | FDA Document Number *(if known)* |

**SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**

| | | | |
|---|---|---|---|
| ☒ Original ☐ Add ☐ Delete | Facility Establishment Identifier (FEI) Number: 2032493 | ☒ Manufacturer ☐ Contract Manufacturer | ☐ Contract Sterilizer ☐ Repackager / Relabeler |
| Company / Institution Name: MicroVention, Inc. | | Establishment Registration Number: 2032493 | |
| Division Name *(if applicable)* | | Phone Number *(including area code)*: 714-247-8000 | |
| Street Address: 1311 Valencia Avenue | | FAX Number *(including area code)*: 714-247-8005 | |
| City: Tustin | State / Province: CA | ZIP Code: 92780 | Country: USA |
| Contact Name: Naomi Gong | Contact Title: Sr. RA Project Manager | Contact E-mail Address: naomi.gong@microvention.com | |

| | | | |
|---|---|---|---|
| ☒ Original ☐ Add ☐ Delete | Facility Establishment Identifier (FEI) Number: | ☐ Manufacturer ☐ Contract Manufacturer | ☒ Contract Sterilizer ☐ Repackager / Relabeler |
| Company / Institution Name: Sterigenics | | Establishment Registration Number: 2011171 | |
| Division Name *(if applicable)* | | Phone Number *(including area code)*: 951-340-0700 | |
| Street Address: 4900 South Griffith Avenue | | FAX Number *(including area code)*: | |
| City: Los Angeles | State / Province: CA | ZIP Code: 90058 | Country: USA |
| Contact Name: Sharon Huges | Contact Title: Representative | Contact E-mail Address: losangelessales@sterigenics.com | |

| | | | |
|---|---|---|---|
| ☐ Original ☐ Add ☐ Delete | Facility Establishment Identifier (FEI) Number: | ☐ Manufacturer ☐ Contract Manufacturer | ☐ Contract Sterilizer ☐ Repackager / Relabeler |
| Company / Institution Name: | | Establishment Registration Number: | |
| Division Name *(if applicable)* | | Phone Number *(including area code)*: | |
| Street Address: | | FAX Number *(including area code)*: | |
| City: | State / Province: | ZIP Code: | Country: |
| Contact Name: | Contact Title: | Contact E-mail Address: | |

## SECTION I UTILIZATION OF STANDARDS

**Note:** Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

| | Standards No. | Standards Organization | Standards Title | Version | Date |
|---|---|---|---|---|---|
| **1** | | | | | |
| **2** | Standards No. | Standards Organization | Standards Title | Version | Date |
| **3** | Standards No. | Standards Organization | Standards Title | Version | Date |
| **4** | Standards No. | Standards Organization | Standards Title | Version | Date |
| **5** | Standards No. | Standards Organization | Standards Title | Version | Date |
| **6** | Standards No. | Standards Organization | Standards Title | Version | Date |
| **7** | Standards No. | Standards Organization | Standards Title | Version | Date |

**Please include any additional standards to be cited on a separate page.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.*

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.


## 1.3. Truthful and Accuracy Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Sr. Regulatory Affairs Project Manager of MicroVention, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

_____
(Signature)

Naomi Gong
(Typed Name)

_____
(Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.


## 1.4. 510(k) Summary

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

# 510(k) Summary

| | |
|---|---|
| **Trade Name:** | SOFIA Distal Access Catheter |
| **Generic Name:** | Percutaneous Catheter |
| **Classification:** | Class II, 21 CFR 870.1250 (DQY) |
| **Submitted By:** | MicroVention, Inc<br>1311 Valencia Avenue<br>Tustin, California U.S.A. |
| **Contact:** | Naomi Gong |
| **Date:** | 2013 May 21 |
| **Predicate Device:** | Chaperon Guiding Catheter (K082385) |

**Device Description:**

The SOFIA™ Distal Access Catheter is a single-lumen, flexible catheter designed with coil and braid reinforcement. The distal segment is steam-shapeable and it has a hydrophilic coating for navigation through the vasculature. The radiopaque marker is located at the distal end of the catheter for visualization under fluoroscopy. An introducer sheath and shaping mandrel are also provided.

**Indications For Use:**

The SOFIA™ Distal Access Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA™ Distal Access Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. The SOFIA™ Distal Access Catheter is not intended for use in coronary arteries.

**Verification and Test Summary:**

| Bench Testing | Result |
|---|---|
| Surface and physical attributes | Pass |
| Distal tensile strength | Pass |
| Hub tensile strength | Pass |
| Hub test (ISO 594-2) | Pass |
| Leakage (liquid and air) | Pass |
| Static and dynamic burst pressure | Pass |
| Simulated use | Pass |
| Durability/lubricity of hydrophilic coating | Pass |
| Compatibility with devices | Pass |
| Flow rate | Pass |
| Kink resistance | Pass |
| Catheter stiffness | Pass |
| Radio-detectability | Pass |
| Catheter flexural fatigue | Pass |

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

| | |
|---|---|
| Torque strength | Pass |
| Particulate test | Pass |
| Tip shapeability | Pass |
| **Biocompatibility** | **Result** |
| Cytotoxcitiy (ISO 10993-5)<br>- MEM elution assay<br>- Agarose overlay | Pass |
| Sensitization/Irritation (ISO 10993-10)<br>- Guinea pig maximization sensitization<br>- Intracutaneous reactivity | Pass |
| Hemocompatibility (ISO 10993-4)<br>- Hemolysis<br>- Prothrombin time assay<br>- Complement activation C3a and SC5b-9<br>- 4 hour thromboresistance in dogs | Pass |
| Systemic Toxicity (ISO 10993-11)<br>- Systemic toxicity<br>- Rabbit pyrogen test | Pass |

**Technological Comparison:**

| | **Chaperon Guiding Catheter** | **SOFIA Distal Access Catheter** |
|---|---|---|
| Intended Use | Intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries. | Same |
| Material | Outer layer of polyester elastomer, stainless steel braid, inner liner of PTFE (polytetrafluoroehthylene).<br>Tungsten radiopaque marker, nylon hub, and polyester elastomer strain relief. | Outer layer of polyolefin elastomer, polyurethane elastomer , polyether block amide; inner layer of PTFE, stainless steel braid and coil.<br>Pt/Ir radiopaque marker, nylon hub, polyurethane strain relief.<br>Pebax introducer sheath and stainless steel shaping mandrel. |
| Catheter size | 5F (Outer catheter) | Same |
| ID | 1.5 mm | 1.4 mm |
| OD | 1.7 mm | Same |
| Effective Length | Outer: 95 cm<br>Inner: 117 cm | 125 cm |
| Coating | Yes | Same |
| Tip Configuration | Preshaped | Steam shapeable by user |
| Guidewire compatibility | 0.035" or 0.038" | Same |
| Accessories | N/A | Introducer sheath and shaping mandrel |

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**Summary of Substantial Equivalence:**

The data presented in this submission demonstrates the technological similarity and equivalency of the SOFIA Distal Access Catheter when compared with the predicate device, Chaperon Guiding Catheter (K082385).

The devices,

- Have the same intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Are packaged and sterilized using same methods.

In summary, the SOFIA Distal Access Catheter described in this submission is substantially equivalent to the predicate device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.


## 1.5. Indications for Use

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

# Indications for Use

510(k) Number (if known):_____

Device Name: SOFIA™ Distal Access Catheter

Indications For Use:

*The SOFIA Distal Access Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries.*

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.


## 1.6. Form FDA 3674

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**FOOD AND DRUG ADMINISTRATION**

# Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

Form Approved: OMB No. 0910-0616
Expiration Date: 06-30-2008
See OMB Statement on Reverse

## SPONSOR/APPLICANT/SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER

Naomi Gong

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

May 21, 2013

3. ADDRESS (*Number, Street, State, and Zip Code*)

MicroVention, Inc.
1311 Valencia Avenue
Tustin, CA 92780

4. TELEPHONE AND FAX NUMBER (*Include Area Code*)

(T) +1 (714) 247-8005
(F) +1 (714) 247-8014

## PRODUCT INFORMATION

5. FOR DRUGS/BIOLOGICS: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s) (*Attach extra pages as necessary*)

SOFIA Distal Access Catheter

## APPLICATION/SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (*If number previously assigned*)

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

## CERTIFICATION STATEMENT/INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (*See instructions for additional information and explanation*)

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN # 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (*Attach extra pages as necessary*)

NCT Number(s)

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The undersigned declares, to the best of his/her knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

| 11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (SIGN) | 12. NAME AND TITLE OF THE PERSON WHO SIGNED IN #11 |
|---|---|
| | Naomi Gong<br>Sr. Regulatory Affairs Project Manager |
| 13. ADDRESS (*Number, Street, State, and Zip Code*) *(of person identified in #11 & 12)* | 14. TELEPHONE AND FAX NUMBER (*Include Area Code*) |
| 1311 Valencia Avenue<br>Tustin, CA 92780 | (T) +1 (714) 247-8055<br>(F) +1 (714) 247-8014 |

15. DATE OF CERTIFICATION May 21, 2013

***Paperwork Reduction Act Statement***

Public Reporting Burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the applicable address below.

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Form No. FDA 3674
5901-B Ammendale Road
Beltsville, MD 20705-1266

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
Center for Devices and Radiological Health
Program Operations Staff (HFZ-403)
9200 Corporate Blvd.
Rockville, MD 20850

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.*

Records Processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

## Instructions for Completion of Form FDA 3674

**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

**1. Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.

**2. Date** - This is the date of the application/submission which the certification accompanies.

**3. & 4.** - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.

**5. Product Information** - For Drugs/Biologics: Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/ submission. Include all available names by which the product is known.
For Devices: Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.

**6. Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."

**7. IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.

**8. Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field.

**9. Certification** - This section contains three different check-off boxes.

Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply to any of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply at the time of submission to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

**10. National Clinical Trial (NCT) Numbers** - If you have checked Box C in # 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as NCT will be added automatically before number. Include any and all NCT numbers assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

**11. Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.

**12. Name and Title of Person Who Signed in #11.** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.

**13. & 14. & 15.** - Provide the full address, telephone and fax number of the person who is identified in number 11 and signs the certification in number 12. Provide the date the certification is signed. This date may be different from the date provided in #2.

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## 1.7. Form FDA 3654

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

# STANDARDS DATA REPORT FOR 510(k)s

**(To be filled in by applicant)**

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10555-1: 2004, Sterile single use intravascular catheters

| **Please answer the following questions** | Yes | No |
|---|---|---|
| Is this standard recognized by FDA [2]? | ☒ | ☐ |
| FDA Recognition number [3] | #6-161 | |
| Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? | ☐ | ☒ |
| Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table. | ☒ | ☐ |
| Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? | ☒ | ☐ |
| Does this standard include acceptance criteria? If no, include the results of testing in the 510(k). | ☒ | ☐ |
| Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table. | ☐ | ☒ |
| Were there any deviations or adaptations made in the use of the standard? | ☐ | ☒ |
| If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]? | ☐ | ☐ |
| Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table. | ☐ | ☒ |
| Were there any exclusions from the standard? If yes, report these exclusions in the summary report table. | ☐ | ☒ |
| Is there an FDA guidance [6] that is associated with this standard? | ☒ | ☐ |
| If yes, was the guidance document followed in preparation of this 510k? | ☒ | ☐ |

Title of guidance: Guidance on 510k submission for short and long-term intravascular cahteter (1995)

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.
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## EXTENT OF STANDARD CONFORMANCE
## SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10555-1: 2004, Sterile single use intravascular catheters

### CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| All | (as applicable) | ☒ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

### Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

# STANDARDS DATA REPORT FOR 510(k)s

**(To be filled in by applicant)**

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14971:20012 Medical Device - Application of Risk Management to Medical Devices

| **Please answer the following questions** | Yes | No |
|---|---|---|
| Is this standard recognized by FDA [2]? | ☒ | ☐ |
| FDA Recognition number [3] # 5-40 | | |
| Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? | ☐ | ☒ |
| Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table. | ☐ | ☒ |
| Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? | ☒ | ☐ |
| Does this standard include acceptance criteria? If no, include the results of testing in the 510(k). | ☐ | ☒ |
| Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table. | ☐ | ☒ |
| Were there any deviations or adaptations made in the use of the standard? | ☐ | ☒ |
| If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]? | ☐ | ☐ |
| Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table. | ☐ | ☒ |
| Were there any exclusions from the standard? If yes, report these exclusions in the summary report table. | ☐ | ☒ |
| Is there an FDA guidance [6] that is associated with this standard? | ☐ | ☒ |
| If yes, was the guidance document followed in preparation of this 510k? | ☐ | ☐ |

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.
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## EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 14971:2012, Medical Device - Application of Risk Management to Medical Devices

### CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| All | (as applicable) | ☒ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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Department of Health and Human Services
Food and Drug Administration

# STANDARDS DATA REPORT FOR 510(k)s

**(To be filled in by applicant)**

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

EN 556-1:2001, Sterilization of medical devices, Requirement for medical devices designated "Sterile"

| **Please answer the following questions** | Yes | No |
|---|---|---|
| Is this standard recognized by FDA [2]? | ☒ | ☐ |
| FDA Recognition number [3] | # N/A | |
| Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? | ☐ | ☒ |
| Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table. | ☐ | ☒ |
| Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? | ☒ | ☐ |
| Does this standard include acceptance criteria? If no, include the results of testing in the 510(k). | ☐ | ☒ |
| Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table. | ☐ | ☒ |
| Were there any deviations or adaptations made in the use of the standard? | ☐ | ☒ |
| If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]? | ☐ | ☐ |
| Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table. | ☐ | ☒ |
| Were there any exclusions from the standard? If yes, report these exclusions in the summary report table. | ☐ | ☒ |
| Is there an FDA guidance [6] that is associated with this standard? | ☐ | ☒ |
| If yes, was the guidance document followed in preparation of this 510k? | ☐ | ☐ |

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.
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## EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN 556-1:2001, Sterilization of medical devices, Requirement for medical devices designated "Sterile"

### CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| All | (as applicable) | ☒ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

# STANDARDS DATA REPORT FOR 510(k)s

**(To be filled in by applicant)**

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11135-1:2007, Sterilization of health care products - Ethylene oxide - Part 1

| **Please answer the following questions** | Yes | No |
|---|---|---|
| Is this standard recognized by FDA [2]? | ☒ | ☐ |
| FDA Recognition number [3] | #14-228 | |
| Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? | ☐ | ☒ |
| Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table. | ☐ | ☒ |
| Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? | ☒ | ☐ |
| Does this standard include acceptance criteria? If no, include the results of testing in the 510(k). | ☐ | ☒ |
| Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table. | ☐ | ☒ |
| Were there any deviations or adaptations made in the use of the standard? | ☐ | ☒ |
| If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]? | ☐ | ☐ |
| Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table. | ☐ | ☒ |
| Were there any exclusions from the standard? If yes, report these exclusions in the summary report table. | ☐ | ☒ |
| Is there an FDA guidance [6] that is associated with this standard? | ☐ | ☒ |
| If yes, was the guidance document followed in preparation of this 510k? | ☐ | ☐ |

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.
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## EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 11135-1:2007, Sterilization of health care products - Ethylene oxide - Part 1

### CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| All | (as applicable) | ☒ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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**Paperwork Reduction Act Statement**

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

# STANDARDS DATA REPORT FOR 510(k)s

**(To be filled in by applicant)**

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 13485:2003/2009 Particular requirement for application of ISO 9001

| Please answer the following questions | Yes | No |
|---|---|---|
| Is this standard recognized by FDA [2]? | ☒ | ☐ |
| FDA Recognition number [3] # N/A | | |
| Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? | ☐ | ☒ |
| Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table. | ☐ | ☒ |
| Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? | ☒ | ☐ |
| Does this standard include acceptance criteria? If no, include the results of testing in the 510(k). | ☐ | ☒ |
| Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table. | ☐ | ☒ |
| Were there any deviations or adaptations made in the use of the standard? | ☐ | ☒ |
| If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]? | ☐ | ☐ |
| Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table. | ☐ | ☒ |
| Were there any exclusions from the standard? If yes, report these exclusions in the summary report table. | ☐ | ☒ |
| Is there an FDA guidance [6] that is associated with this standard? | ☐ | ☒ |
| If yes, was the guidance document followed in preparation of this 510k? | ☐ | ☐ |

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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## EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 13485:2003/2009, Particular requirement for application of ISO 9001

### CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| All | (as applicable) | ☒ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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# STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-1:2010, Biological Evaluation of Medical Devices

| **Please answer the following questions** | Yes | No |
|---|---|---|
| Is this standard recognized by FDA [2]? | ☒ | ☐ |
| FDA Recognition number [3] | #2-98 | |
| Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? | ☒ | ☐ |
| Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table. | ☒ | ☐ |
| Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? | ☒ | ☐ |
| Does this standard include acceptance criteria? If no, include the results of testing in the 510(k). | ☐ | ☒ |
| Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table. | ☐ | ☒ |
| Were there any deviations or adaptations made in the use of the standard? | ☐ | ☒ |
| If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]? | ☐ | ☐ |
| Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table. | ☐ | ☒ |
| Were there any exclusions from the standard? If yes, report these exclusions in the summary report table. | ☐ | ☒ |
| Is there an FDA guidance [6] that is associated with this standard? | ☒ | ☐ |
| If yes, was the guidance document followed in preparation of this 510k? | ☒ | ☐ |

Title of guidance: FDA Blue Book Memorandum G95-1

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## EXTENT OF STANDARD CONFORMANCE
## SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-1:2010, Biological Evaluation of Medical Devices

**CONFORMANCE WITH STANDARD SECTIONS***

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| All | (as applicable) | ☒ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

EN 980:2008, Graphical symbol used in labeling of Medical Devices

| **Please answer the following questions** | Yes | No |
|---|---|---|
| Is this standard recognized by FDA [2]? | ☒ | ☐ |
| FDA Recognition number [3] # N/A | | |
| Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? | ☐ | ☒ |
| Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table. | ☐ | ☒ |
| Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? | ☒ | ☐ |
| Does this standard include acceptance criteria? If no, include the results of testing in the 510(k). | ☐ | ☒ |
| Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table. | ☐ | ☒ |
| Were there any deviations or adaptations made in the use of the standard? | ☐ | ☒ |
| If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]? | ☐ | ☐ |
| Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table. | ☐ | ☒ |
| Were there any exclusions from the standard? If yes, report these exclusions in the summary report table. | ☐ | ☒ |
| Is there an FDA guidance [6] that is associated with this standard? | ☐ | ☒ |
| If yes, was the guidance document followed in preparation of this 510k? | ☐ | ☐ |

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

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## EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN 980:2008, Graphical symbol used in labeling of Medical Devices

### CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| All | (as applicable) | ☒ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11607-1, -2:2006, Packaging for Terminally Sterilized Medical Devices

| **Please answer the following questions** | Yes | No |
|---|---|---|
| Is this standard recognized by FDA [2]? | ☒ | ☐ |
| FDA Recognition number [3] | # 14-193, 14-194 | |
| Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? | ☐ | ☒ |
| Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table. | ☐ | ☒ |
| Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? | ☒ | ☐ |
| Does this standard include acceptance criteria? If no, include the results of testing in the 510(k). | ☐ | ☒ |
| Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table. | ☐ | ☒ |
| Were there any deviations or adaptations made in the use of the standard? | ☐ | ☒ |
| If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]? | ☐ | ☐ |
| Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table. | ☐ | ☒ |
| Were there any exclusions from the standard? If yes, report these exclusions in the summary report table. | ☐ | ☒ |
| Is there an FDA guidance [6] that is associated with this standard? | ☐ | ☒ |
| If yes, was the guidance document followed in preparation of this 510k? | ☐ | ☐ |

Title of guidance: _____

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## EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 11607-1, -2:2006, Packaging for Terminally Sterilized Medical Devices

### CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| All | (as applicable) | ☒ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

EN 1041: 2008, Terminology, Symbols, and Information Supplied with Devices

| **Please answer the following questions** | Yes | No |
|---|---|---|
| Is this standard recognized by FDA [2]? | ☒ | ☐ |
| FDA Recognition number [3] | # N/A | |
| Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? | ☐ | ☒ |
| Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table. | ☐ | ☒ |
| Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? | ☒ | ☐ |
| Does this standard include acceptance criteria? If no, include the results of testing in the 510(k). | ☐ | ☒ |
| Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table. | ☐ | ☒ |
| Were there any deviations or adaptations made in the use of the standard? | ☐ | ☒ |
| If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]? | ☐ | ☐ |
| Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table. | ☐ | ☒ |
| Were there any exclusions from the standard? If yes, report these exclusions in the summary report table. | ☐ | ☒ |
| Is there an FDA guidance [6] that is associated with this standard? | ☐ | ☒ |
| If yes, was the guidance document followed in preparation of this 510k? | ☐ | ☐ |

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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## EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
EN 1041: 2008, Terminology, Symbols, and Information Supplied with Devices

### CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| All | (as applicable) | ☒ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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## 1.8. Declaration of Conformity

# Declaration of Conformity With Design Controls

**SOFIA Distal Access Catheter**

**Verification Activities:**

To the best of my knowledge, the verification activities required by the risk analysis, for the above referenced device were performed by the designated individual(s) in accordance with the MicroVention Quality Procedure Design and Development Process requirements, and the results demonstrated that the predetermined acceptance criteria were met.

Joe Gulachenski — 5-16-2013
Joe Gulachenski — Date
Director of Research and Development

==========

**Manufacturing Facility:**

The manufacturing facility, MicroVention Inc., is in conformance with the design control requirements as specified in 21 CFR 820.30, and the records are available for review.

Tom Sternweiler — 5-16-13
Tom Sternweiler — Date
Senior Director of Quality

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## 1.9. Design Control Activities Summary

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## SOFIA Catheter - Design Control Activities Summary

| Device Modification | Risk | Verification Activity | Acceptance Criteria | Results of Verification |
|---|---|---|---|---|
| **Predicate Device:** Chaperon Guiding Catheter (K082385) | | | | |
| 1. Catheter length<br>Chaperon (predicate): 95-117 cm<br>SOFIA: 125 cm<br><br>2. Catheter ID<br>Chaperon: 1.5 mm<br>SOFIA: 1.4 mm<br><br>3. Radiopaque marker<br>Chaperon: Imbedded tungsten<br>SOFIA: Pt/Ir marker band<br><br>4. Hydrophilic coating<br>Both have, but SOFIA is the same as Headway DUO (K120917)<br><br>5. Tip configuration<br>Chaperon: Preshaped<br>SOFIA: Steam shapeable by user<br><br>6. Additions to SOFIA<br>i. A stainless steel coil (304V) over the inner liner (length of minimum 15 cm to the distal tip)<br>ii. The distal outer shaft consists of different durometers and different lengths of polyblend 1100, pellethane 80A and Plexar 3080 of natural color. The range of polyblend durometers is between 30A to 60A | All modifications were evaluated for risk and were determined to be tolerable. | **Bench Testing:**<br>1. Surface contamination<br>2. Physical Attributes<br>3. Simulated use, insertion tool performance and equipment interface<br>4. Kink resistance<br>5. Tip shapeability<br>6. Radio detectability<br>7. Hub (ISO 594-2)<br>8. Durability/Lubricity of hydrophilic coating<br>9. Catheter stiffness testing<br>10. Torque strength test<br>11. Catheter flexural fatigue<br>12. Force at break (distal and hub)<br>13. Flow rate<br>14. Static burst<br>15. Leakage at 46 psi<br>16. Air Leakage<br>17. Dynamic burst<br>18. Catheter particle testing | Per TP12-280:<br>1. Free from unacceptable conditions per TP12-280.<br>2. Physical attributes criteria per TP11-280<br>3. Simulated use and equipment interface<br>4. Equivalent to or better kink resistance than competitor products during simulated use testing (rating of 3 or better per TP12-280)<br>5. For reference only<br>6. The catheter must have acceptable results per TP12-280<br>7. Testing meets ISO 594-2<br>8. The catheter must have acceptable results per TP12-280<br>9. Document stiffness for reference use only.<br>10. The catheter must have acceptable results per TP12-280<br>11. The catheter must have acceptable results per TP12-280<br>12. ≥ 2.25 lbf for outer diameters ≥ 0.045" and < 0.072"<br>13. Equivalent to or better flow rates than competitor products (for reference only)<br>14. Catheter shaft will not burst below 46 psi.<br>15. No liquid leaking from hub and catheter shaft at 46 psi for 30 second duration.<br>16. No air leaking into syringe for 15 seconds (ignore air bubbles for the first 5 seconds of the test.<br>17. Catheter will not burst below 300 psi<br>18. Less than 25 particles/ml (> 10 microns) and less than 3 particles/ml (> 25 microns) | All test data met acceptance criteria and results are documented in TR12-280.<br><br>For Verification:<br>• All testing passed with 90% confidence level at 80% reliability<br><br>For Validation:<br>• All testing passed with 90% confidence level of 90% reliability |
| | | **Packaging and Pouch Testing:** | Per TP12-288 | Met acceptance criteria (TR12-288) |



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| | | | | |
|---|---|---|---|---|
| iii. Introducer sheath and shaping mandrel included in packaged device<br>iv. Packaging: Added a dispenser tube to hold the catheter in place on the packaging card | | **Biocompatibility testing** | Per ISO 10993-1 | Met acceptance criteria (Toxikon Reports in Appendix 7) |



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## 2. Executive Summary

The MicroVention SOFIA™ (**S**oft torqueable catheter **O**ptimized **F**or **I**ntracranial **A**ccess) Distal Access Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries.

The SOFIA Catheter is a single lumen catheter designed to be introduced over a steerable guidewire to access small, tortuous vasculature. The semi-rigid proximal section transitions to a flexible distal tip to facilitate advancement through vessels. A single radiopaque marker at the distal end facilitates fluoroscopic visualization. The outer surface of the catheter is coated with a hydrophilic coating to reduce friction during navigation in the vasculature. A luer fitting on the microcatheter hub is used for the attachment of accessories. The hub – strain relief provides kink resistance for the proximal end. A steam shaping mandrel and introducer sheath are also packaged with the catheter.

The SOFIA Catheter has the same intended use as the predicate, Chaperon Guiding Catheter (K082385) and is similar in terms of design and operating principle. The SOFIA Catheter has been designed to facilitate increased trackability and provide greater accessibility to the vasculature. The distal straight tip is designed to be steam shaped by the user at the time of use.

The *in vitro* testing covered the physical, mechanical, and functional performance of the SOFIA Catheter using the FDA Special Controls Draft Guidance Document: Short-Term and Long-Term Intravascular Catheters Dated March 16, 1995 and applicable sections of the ISO 10555-1 international standard for Sterile, Single-Use Intravascular Catheters. These tests validated the performance characterization of the SOFIA Catheter. The combined conclusion from these tests demonstrates that the *in vitro* behavior of device is well characterized within design specifications.

A full panel of biocompatibility tests was conducted according to ISO10993-1 and provides assurance that the device has a safe biocompatibility profile for use as an externally communicating, circulating blood, limited contact (≤ 24 hrs) device.

The SOFIA Catheter is intended to be sold sterile, for single use. The sterilization method (ethylene oxide) has been validated as well as the packaging configuration.

It is on this basis that it can be concluded the safety profile of SOFIA Catheter is well within acceptable safety limits to be used for its indications for use.

*Note: During the product development, some of the documents reference Hybrid Access Catheter (HAC), Distal Access Catheter (DAC), or Project # RD11-012. These are all previous names used for the SOFIA Distal Access Catheter (final product name of the device).*

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## 3. Device Name

The device trade names and common/classification names are:

| | |
|---|---|
| Device Trade Name | SOFIA Distal Access Catheter |
| Device Generic Name | Percutaneous Catheter |
| Classification Name | Percutaneous Catheter |
| CFR Classification | 21 CFR 870.1250 |
| Device Class | Class II |
| Classification Committee | Cardiovascular |
| Product Code | DQY |

## 4. Address and Registration Number

The address and registration number of the manufacturer and sterilization sites for the device are:

| | |
|---|---|
| **Manufacturer** | MicroVention, Inc.<br>1311 Valencia Avenue<br>Tustin, California U.S.A |
| **Establishment Registration No.** | 2032493 |
| **Contact** | Naomi Gong<br>Sr. Regulatory Affairs Project Manager<br>1311 Valencia Avenue<br>Tustin, California U.S.A.<br>Phone: (714) 247-8055<br>Fax: (714) 247-8014 |
| **Sterilization Site** | Sterigenics<br>4900 South Griffith Ave.<br>Los Angeles, California, 90058<br>FDA Registration No= 2011171 |

## 5. Device Class

The SOFIA Catheter is a percutaneous catheter and is classified as Class II, DQY. The product has been designed, developed and tested using the FDA Guidance 510(k) Submission for Short-Term and Long-Term Intravascular Catheters (1995).

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## 6. Predicate Device Information

K082385, MicroVention, Inc., Chaperon Guiding Catheter

## 7. Labeling and Intended Use

Draft labels and Instructions For Use are provided in Appendix 1.

**Intended Use**

The intended use is the same as the predicate device, Chaperon Guiding Catheter and is stated in the product labeling as follows:

*The SOFIA™ Distal Access Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries.*

## 8. Device Overview

The SOFIA Catheter is a single lumen (0.055" or 1.4 mm inner diameter) catheter with a shapeable distal tip. The semi-rigid proximal section transitions to a flexible distal tip to facilitate advancement through the vasculature.

A single radiopaque marker (Pt/Ir) at the distal end facilitates fluoroscopic visualization. The outer surface of the catheter (distal 60 cm) is coated with a hydrophilic polymer coating to reduce friction during navigation in the vasculature.

A luer fitting on the microcatheter hub is used for the attachment of accessories. The hub/strain relief provides kink resistance for the proximal end. The tip configuration is provided straight, but is shapeable by the user. A steam shaping mandrel and introducer sheath accessories are packaged with the catheter.

The device is placed in a dispenser tube to keep the device in position during shipping and handling. The dispenser tube is placed on a packaging card and then placed into a tyvek pouch. The pouch is put into a chipboard carton box prior to sterilization. The device is provided sterile, for single use.

## 9. Device Configurations and Dimensions

The SOFIA Distal Access Catheter has an inner lumen of 0.055" and is recommended to be used with guidewires from 0.035" to 0.038".

| Device | Catalogue Number | Working Length | Outer Diameter/ Inner Diameter | Recommended Guidewire |
|---|---|---|---|---|
| SOFIA Distal Access Catheter | DA5125ST | 125 mm | 0.068"/0.055" (1.7/1.4 mm) | 0.035" to 0.038" |

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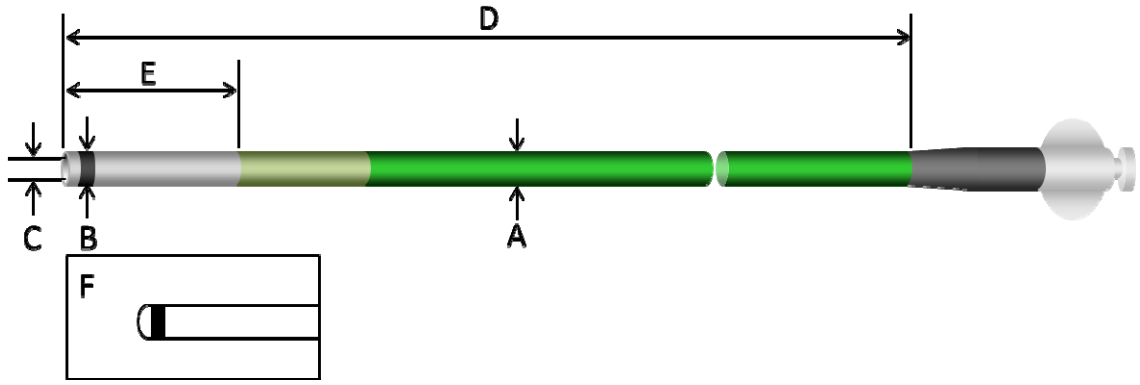
# 10. Design Description

The SOFIA Catheter is a stainless steel braid plus coil reinforced, a single lumen, variable stiffness catheter with a shapeable distal segment. It consists of a lubricious inner liner and a radiopaque marker located at distal tip to facilitate fluoroscopic visualization. The outer distal section of catheter has a hydrophilic coating for lubricious insertion and delivery. The semi-rigid proximal section transitions to a flexible distal tip to facilitate advancement through vessels.

**SOFIA Catheter (not to scale)**




| | | |
|---|---|---|
| A | Diameter (outer), proximal | 0.068 in/ 1.7 mm |
| B | Diameter (outer), distal | 0.068 in/ 1.7 mm |
| C | Diameter (inner) | 0.055 in |
| D | Working length | 125 cm |
| E | Distal section | 16 cm |
| F | Tip configuration | Straight Shapeable |

The catheter body is constructed with a stainless steel coil (less 2 cm of catheter length) over the inner lumen liner comprised of polytetrafluoroethylene (PTFE) and polyolefin elastomer. To provide additional shaft support, a stainless steel wire braiding has been added over the stainless steel coil from the proximal end to distal end. A platinum/iridium alloy radiopaque marker band is located at the distal tip of the catheter. This is all covered by an outer layer of varying durometers of polyurethane and polyether block amide.

The outer layer consists of a range durometers and lengths of polyurethane (Polyblend and Pellethane) and polyether block amide (Pebax) - distal and proximal, respectively. The most proximal outer shaft section consists of a polyamide (Grilamid).

A nylon hub is attached to the proximal end of the catheter. A strain relief made from polyurethane is placed at the proximal end of the catheter and distal end of the hub.

The outer surface of the catheter (distal 60 cm) is coated with a hydrophilic coating to reduce friction during navigation in the vasculature.

A luer fitting on the catheter hub is used for the attachment of accessories. The hub – strain relief provides for the kink resistance from the proximal end.

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A steam shaping (stainless steel) mandrel with an outer diameter of 0.0255" is provided with the catheter to be used by the physician for tip shaping. An introducer sheath (Pebax) is also included to facilitate the introduction of the catheter into the y-connector. These two components are the identical to the Headway Duo with the exception of dimensional differences to accommodate the ID/OD of the SOFIA Catheter.

The device is provided sterile and for single use. The catheter is placed in a dispenser tube (HDPE) and is placed on a packaging card (polyethylene) that is provided in a sterile barrier tyvek pouch and placed in a carton box.

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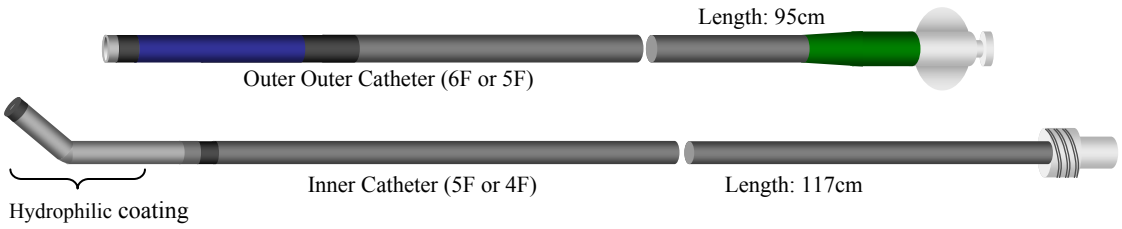
The predicate Chaperon Guiding Catheter is a two-catheter system comprised of the outer catheter and the inner catheter. The Chaperon Guiding Catheter system can be used individually with 0.035" or 0.038" guidewire or together with the Inner Catheter to access the desired anatomy.

**Chaperon Guiding Catheter**




The SOFIA has the same basic design of the Outer catheter, but incorporates a hydrophilic coating like that of the Inner catheter.

Sample product drawing for the SOFIA Distal Access Catheter is provided in the Appendix 2.

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## 11. Technological Characteristics Comparison

The following table compares the technological characteristics of the SOFIA Catheter to the predicate device, Chaperon.

| | Chaperon Guiding Catheter – K082385 (Outer catheter) | SOFIA Distal Access Catheter |
|---|---|---|
| Intended Use | Intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries. | Same |
| Material | Outer layer of polyester elastomer, stainless steel braid, inner liner of PTFE (polytetrafluoroehthylene).<br>Tungsten radiopaque marker, nylon hub, and polyester elastomer strain relief. | Outer layer of polyolefin elastomer, polyurethane elastomer , polyether block amide, polyamide; inner layer of PTFE/polyolefin; stainless steel braid and coil.<br>Pt/Ir radiopaque marker, nylon hub, polyurethane strain relief.<br>Pebax introducer sheath and stainless steel shaping mandrel. |
| Catheter size | 5F (Outer catheter) | Same |
| ID | 1.5 mm (0.059") | 1.4 mm (0.055") |
| OD | 1.7 mm (0.068") | Same |
| Effective Length | Outer Catheter : 95 cm<br>Inner Catheter: 117 cm | 125 cm |
| Coating | Hydrophilic coating (inner catheter) | Hydrophilic coating (same as Headway Duo, K120917) |
| Tip Configuration | Preshaped | Steam shapeable by user |
| Guidewire compatibility | 0.035" or 0.038" | Same |
| Accessories | N/A | Introducer sheath and shaping mandrel (same as Headway Duo) |
| Packaging | Packaging Card/Tyvek pouch/Carton | Same, with dispenser tube to hold catheter on packaging card |
| Method of supply | Sterile and single use | Same |

## 12. Design Control and Risk Management Processes

The SOFIA Catheter is designed, developed and tested in accordance with the MicroVention Design and Development procedure in which the impact of modifications on device safety and performance is assessed in accordance with the ISO 14971-1 (Medical Device Risk Management) – Part 1, and with the MicroVention quality system procedure for Risk Management. Possible hazards and associated risk related to the device modification and


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clinical usage of the device were identified, examined and found to be acceptable after the implementation of the countermeasures such as physician training program, labeling warnings, specify possible mitigation.

Copies of the relevant procedures and documents are included as shown below:

Attachment 3 – QP 4.1, Design and Development Process procedure
Attachment 4 – QP 4.8, Risk Management procedure
Attachment 5 – RA060004, Risk Assessment and Control Analysis
- FA060010, dFMEA

## 13. List of Voluntary Standards

The SOFIA Catheter was designed, developed, and tested using the applicable requirements of the following standards:

| Standard No. | Standard Name | Edition |
|---|---|---|
| FDA Guidance | Guidance on Premarket Notification 510(k) Submission for Short-term and Long-term Intravascular Catheter | 1995 |
| ISO 10555-1 | Sterile, Single Use Intravascular Catheters | 2004 |
| Medical Device Directive | Council Directive 93/42/EEC | 2003/2007 |
| ISO/EN 14971 | Medical Device – Application of Risk Management to medical devices | 2012 |
| ANSI/AAMI/ISO11135 | Medical Devices - Validation and routine control of ethylene oxide sterilization, overkill method | 2007 |
| EN 556-1 | Sterilization of medical devices, Requirements for medical devices designated "STERILE" | 2001 |
| ISO 13485 | Particular requirement for application of ISO 9001 | 2003/2009 |
| ISO 10993-1 | Biological evaluation of medical devices | 2010 |
| EN 980 | Graphical Symbol used in Labeling of Medical Devices | 2008 |
| ISO 11607 -1, -2 | Packaging for Terminally Sterilized Medical Devices | 2006 |
| EN 1041 | "Terminology, Symbols and Information Supplied with Devices." | 2008 |

## 14. *In-Vitro*/Bench Verification and Shelf Life

The SOFIA Catheter was tested and verified in the laboratory setting according to written protocol TP12-280, Design Verification/Validation and Accelerated Aging Study of HAC (aka SOFIA). All samples met the established design specification and shelf life testing for 6 months for parametric attributes as well as the determined confidence/reliability level for variable data.

The purpose of the study was to evaluate the effects of aging on the physical and functional properties of the balloon catheters assemblies. For these tests, packaged and sterilized catheters are placed in a temperature-controlled oven at 60°C per ASTM-F-1980 for 29 days

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(equivalent to 1 year). Accelerated aging studies are based on the theory that a rise in temperature of 10° C will double the rate of a chemical reaction. The formula used for calculating aging study time period is:

$$\text{Shelf Life} = t \times q^{y}$$

t = Accelerated Exposure Time (Days)

q = Acceleration Factor (Coefficient of Aging)

$$y = \frac{\text{Elevated Storage Temp (°C)} - \text{Ambient Storage Temp (22 °C)}}{10}$$

During the testing, it was found that the Vicat Softening Point for one of the materials (b)(4) Confidential and Proprietary Information – which impacted the leakage (liquid) test. Therefore, additional samples were aged at 45°C for 44 days to simulate 6 months of shelf life and the tests that were impacted were repeated. The tests samples passed all acceptance criteria at 6 months or 1 year, therefore the device will initially be labeled for 6 month shelf life per the testing regimen conducted. The shelf life will be extended as additional aging studies are successfully completed.

**Test Sample Configuration**

| Product | Model |
|---|---|
| SOFIA | DA5125ST |

Side by side testing with competitive devices, Chaperon, ev3 (Covidien) Navien, and Penumbra 5MAX catheters, has also been performed. Design verification test protocol and test report, TP/TR 12-280 are provided in Appendix 6. The following table summarizes the verification/validation/shelf life testing as conducted:

**SOFIA Testing Summary**

| Bench Testing | Acceptance Criteria | Result |
|---|---|---|
| Simulated use, insertion tool performance and equipment interface | Simulated use and equipment interface<br>• Rating of 3 or higher in all test categories per TM11050<br>• Equivalent or better simulated use rating when compare to competitor products<br>• Compatible with ≤ 0.035″ guidewire<br>• Compatible with 6F or larger guide catheter or guiding sheath<br>• Compatible with all common RHVs and stopcocks<br>• Compatible with ≤ 0.027″ microcatheter (Headway)<br>• Ease entering RHV using insertion tool | Passed |
| Physical attributes<br>• Catheter OD<br>• Catheter ID<br>• Catheter working length<br>• Length of distal section | • Catheter OD 0.0660″ – 0.0685″<br>• ≥ 0.055″<br>• 125 ± 2cm and reaches the M1 vessel in the vessel model<br>• ≥ 15cm | Passed |

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| Bench Testing | Acceptance Criteria | Result |
|---|---|---|
| • Length of marker band to distal tip<br>• Total length of proximal hub and strain relief<br>• Strain relief color | • 0.025″ ± 0.005″<br>• Approximately 5cm<br>• Gray | |
| Kink resistance | • Equivalent to or better kink resistance than competitor products during simulated use testing (rating of 3 or better per TM11050)<br>• Equivalent or better kink resistance than competitor products per TM218 (for reference only) | Passed |
| Tip shapeability | For reference only | N/A |
| Radio detectability | Equivalent to or better radiopacity than competitor products | Passed |
| Gauging (ISO 594-2) | Verify gauging pin and hub align in limit planes. | Passed |
| Separation force (ISO 594-2) | Mating parts separation force is greater than 25N. | Passed |
| Unscrewing torque (ISO 594-2) | Catheter luer remains attached after applying an unscrewing torque not less than 0.02N m for a minimum of 10 seconds. | Passed |
| Stress cracking (ISO 594-2) | Verify there are no stress cracks on catheter hub | Passed |
| Ease of assembly (ISO 594-2) | • No resistance observed between the catheter luer and the reference fitting.<br>• Components must fit together securely. | Passed |
| Resistance to overriding (ISO 594-2) | Catheter luer does not override reference fitting threads | Passed |
| Durability/Lubricity of hydrophilic coating | Rating of 3 or higher in tested categories | Passed |
| Catheter stiffness testing | Testing for reference use only. | N/A |
| Torque strength test | 50 rotations without breakage or equivalent to competitive products | Passed |
| Catheter flexural fatigue | Catheter shall have acceptable results from:<br>• Simulated Use<br>• Force at Break<br>• Flow rate<br>• Static burst pressure<br>• Freedom from leakage (liquid) | Passed |
| Surface contamination | • Free from uncured hydrophilic coating.<br>• No surface particulate > 0.02 $mm^2$ per tappi chart. | Passed |

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| Bench Testing | Acceptance Criteria | Result |
|---|---|---|
| | • Free from surface defect/no sharp edges<br>• Embedded particulate acceptable if OD is in specification<br>• Distal tip smooth and round at lumen opening<br>• PTFE liner is not delaminated at distal tip | |
| Force at break (distal and hub) | ≥ 2.25 lbf for outer diameters ≥ 0.045" and < 0.072" | Passed |
| Flow rate | Equivalent to or better flow rates than competitor products (for reference only) | N/A |
| Static burst | Catheter shaft will not burst below 46 psi. | Passed |
| Leakage at 46 psi | No liquid leaking from hub and catheter shaft at 46 psi for 30 second duration. | Passed |
| Air leakage | No air leaking into syringe for 15 seconds (ignore air bubbles for the first 5 seconds of the test. | Passed |
| Dynamic burst | • Equivalent or greater burst pressure than competitor product<br>• Microcatheter will not burst below 300 psi | Passed |
| Catheter particle testing | Less than 25 particles greater than 10 microns and less than 3 particles greater than 25 micron | Passed |

As summarized in the table, SOFIA Testing Summary, the following tests were conducted to establish the performance characteristics of the device:

### 14.1. Simulated Use

To verify that SOFIA Catheter meets the established performance specifications in a clinically simulated environment, MicroVention has tested total of 22 samples of SOFIA. Samples underwent simulated use testing that included delivery, trackability (with and without guidewire), guidewire lock-up, catheter ovalization, microcatheter stability during coil deployment, coil interaction with microcatheter lumen. All samples met the established acceptance criterion of ≥ 3 rating.

The test simulates a neurointerventional embolization procedure using 37°C fluid with catheters, guidewires, and vessel tortuosity.


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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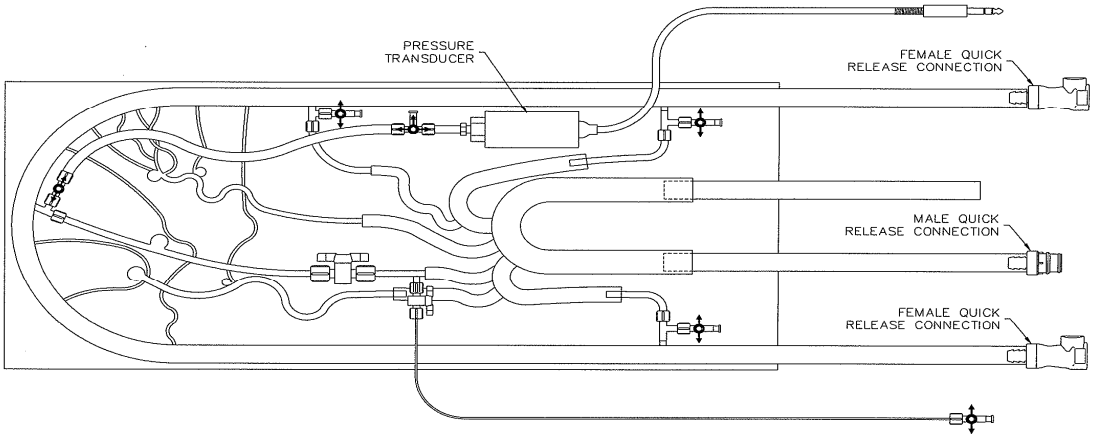


The following table summarizes the results from total of 22 test samples tested using MicroVention SOFIA.

**Simulated Use per TM 11050**

| | SOFIA (1 yr) N = 22 | SOFIA (6 mos) N = 22 | Navien N = 3 | 5MAX N= 3 |
|---|---|---|---|---|
| | Minimum/Maximum rating obtained | | | |
| Preparation/Ease of Assembly | 5/5 | 5/5 | 5/5 | 5/5 |
| Introducer Sheath Interaction | 5/5 | 5/5 | 1/1 | 4/4 |
| Introducer Peel Away | 5/5 | 5/5 | 1/1 | 2/2 |
| Tracking Test with Guidewire/Microcatheter | 4/5 | 5/5 | 1/1 | 3/3 |
| Microcatheter/Guidewire Lockup | 5/5 | 5/5 | 1/1 | 1/1 |
| Lubricity and Durability of Hydrophilic Coating | 4/5 | 4/5 | 1/1 | 1/1 |
| Microcatheter/Guidewire Removal | 5/5 | 5/5 | 1/1 | 1/1 |
| Removal/aspiration of clot | 5/5 | | | |
| Mechanical clot retriever | 4/5 | | | |
| Stent delivery | 5/5 | | | |
| Particles | No particles | No particles | | |
| Acceptance Criteria | Rating ≥ 3 (Scale of 1 -5) | | | |
| Results | Pass | Pass | N/A | N/A |

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As a result of the above testing, guidewires of 0.035" and 0.038" were determined to be compatible for use with the SOFIA.

## 14.2. Dimensional & Physical Attributes

The purpose of this inspection is to 1) verify that finished catheter meet dimensional specifications; and, 2) to ensure integrity of these units subsequently used for physical verification tests. A microscope and standard measuring scales are used for verification of defined dimensions. Results are summarized below:

| Specification (N= 11) | Catheter OD | | | Catheter ID | Overall Working Length |
|---|---|---|---|---|---|
| | 0.0660in. – 0.0685in. (1.68mm – 1.74mm) | | | ≥ 0.055in. (1.40mm) | 125 ± 2cm (49.2 ± 0.8in.) |
| | Distal Tip OD | Distal OD | Proximal OD | | |
| **Min** | 0.0665 (1.69) | 0.0675 (1.71) | 0.0660 (1.68) | NA | 123 (48.4) |
| **Max** | 0.0675 (1.71) | 0.0680 (1.73) | 0.0665 (1.69) | NA | 125 (48.4) |
| **Average** | 0.0670 (1.70) | 0.0677 (1.72) | 0.0660 (1.68) | 0.055 (1.40) | 124.3 (48.9) |
| **St. Dev.** | 0.0005 (0.013) | 0.0003 (0.008) | 0.0002 (0.005) | NA | 0.8 (0.3) |
| **Results** | All units in test group met the criteria – PASS | | | | |

| Specification (N=11) | Length of Distal Section | Length of distal tip to marker band | Total length of hub and strain relief |
|---|---|---|---|
| | ≥ 15cm (5.9in.) | 0.025in. ± 0.005in. (0.635 ± 0.127mm) | Approximately 5cm (1.97in.) |
| **Min** | 15.5 (6.1) | 0.022 (0.559) | NA |
| **Max** | 17.5 (6.9) | 0.029 (0.737) | NA |
| **Average** | 16.1 (6.3) | 0.025 (0.635) | 5.5 (2.2) |
| **St. Dev.** | 0.6 (0.2) | 0.0021 (0.0533) | NA |
| **Results** | All units in test group met the criteria – PASS | | |

## 14.3. Kink Resistance

The purpose of the test is to assess kink resistance of SOFIA Catheter when tested side-by-side with the Navien and 5MAX. Results are then correlated to the data recorded from kink test fixture – smallest bend diameter at which the catheter begins to kink.

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## Kink Resistance (Minimum bend diameter at kink point)

| Distance from distal tip | 1cm (0.39in.) | 4cm (1.57in.) | 12cm (4.72in.) | 25cm (9.84in.) |
|---|---|---|---|---|
| SOFIA (N = 11) | No units kinked using 0.030in. (0.076cm) pin gauge | No units kinked using 0.030in. (0.076cm) pin gauge | No units kinked using 0.030in. (0.076cm) pin gauge | No units kinked using 0.250in. (0.635cm) pin gauge |
| Chaperon (N=3) | No units kinked using 0.030in. (0.076cm) pin gauge | No units kinked using 0.030in. (0.076cm) pin gauge | No units kinked using 0.030in. (0.076cm) pin gauge | No units kinked using 0.170in. (0.432cm) pin gauge |
| Navien (N=3) | All units kinked using 0.080in. (0.203cm) pin gauge | All units kinked using 0.080in. (0.203cm) pin gauge | All units kinked using 0.080in. (0.203cm) pin gauge | All units kinked using 0.250in. (0.635cm) pin gauge |
| 5 MAX | No units kinked using 0.080in. (0.203cm) pin gauge | No units kinked using 0.080in. (0.203cm) pin gauge | All units kinked using 0.080in. (0.203cm) pin gauge | All units kinked using 0.250in. (0.635cm) pin gauge |
| Specification | For Reference data only | | | |

## Kink Resistance (Simulated Use Testing)

| | SOFIA (1 yr) | SOFIA (6 mos) | Navien | 5 MAX |
|---|---|---|---|---|
| | Minimum/Maximum rating obtained | | | |
| N | 22 | 22 | 3 | 3 |
| Track test w/ guidewire | 4/5 | 4/5 | 1/1 | 3/3 |
| Guidewire lock up | 5/5 | 5/5 | 1/1 | 1/1 |
| Acceptance Criteria | Equivalent or better than competitive device | | | |
| Pass/Fail | Pass | Pass | N/A | N/A |

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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## 14.4. Tip Shapeability

The objective of this test is to characterize shapeability distal-tip after steam-shaping. Results are listed below:

**Tip Shapeability**

| | For reference only | | | | | |
|---|---|---|---|---|---|---|
| | SOFIA (N = 11) | | Navien 058 (N = 3) | | 5 MAX (N = 3) | |
| | Steam shaping tip angle | Tip angle measured after steam shaping | Steam shaping tip angle | Tip angle measured after steam shaping | Steam shaping tip angle | Tip angle measured after steam shaping |
| Min | 90.53 | 52.02 | 90.20 | 64.97 | 90.18 | 75.65 |
| Max | | 67.36 | | 83.66 | | 86.32 |
| Average | | 61.10 | | 71.73 | | 79.94 |
| St. Dev. | | 4.34 | | 10.36 | | 5.64 |

## 14.5. Radio-detectibility

The purpose of this test is to compare the radiopacity under angiographic test comparing the SOFIA to the Chaperon and Navien 058. The results are summarized below:

| | Radiopacitiy Test |
|---|---|
| Specification | Marker band radiopacity equivalent to or better than competitor products |
| Results | Distal marker band visible under fluoroscopy. Image intensity equal to that of predicate products. |
| Pass/Fail | Pass |

## 14.6. Hub Evaluation (ISO 594-2)

The purpose of the test is to assess the hub performance of the microcatheter per ISO 594-2 requirements and methods.

**Hub Testing (ISO 594-2)**

| N = 11 | Acceptance criteria | Results |
|---|---|---|
| Hub gauging | Gauging pin and hub align at limit planes | Pass |
| Separation force | Mating parts separation force is great than 25 N | Pass |
| Unscrewing torque | Microcatheter luer remains attached under unscrewing torque of 0.02Nm for 10 seconds | Pass |
| Resistance to override | Microcatheter luer does not override reference fitting threads | Pass |
| Stress cracking | No stress cracks on the microcatheter hub | Pass |

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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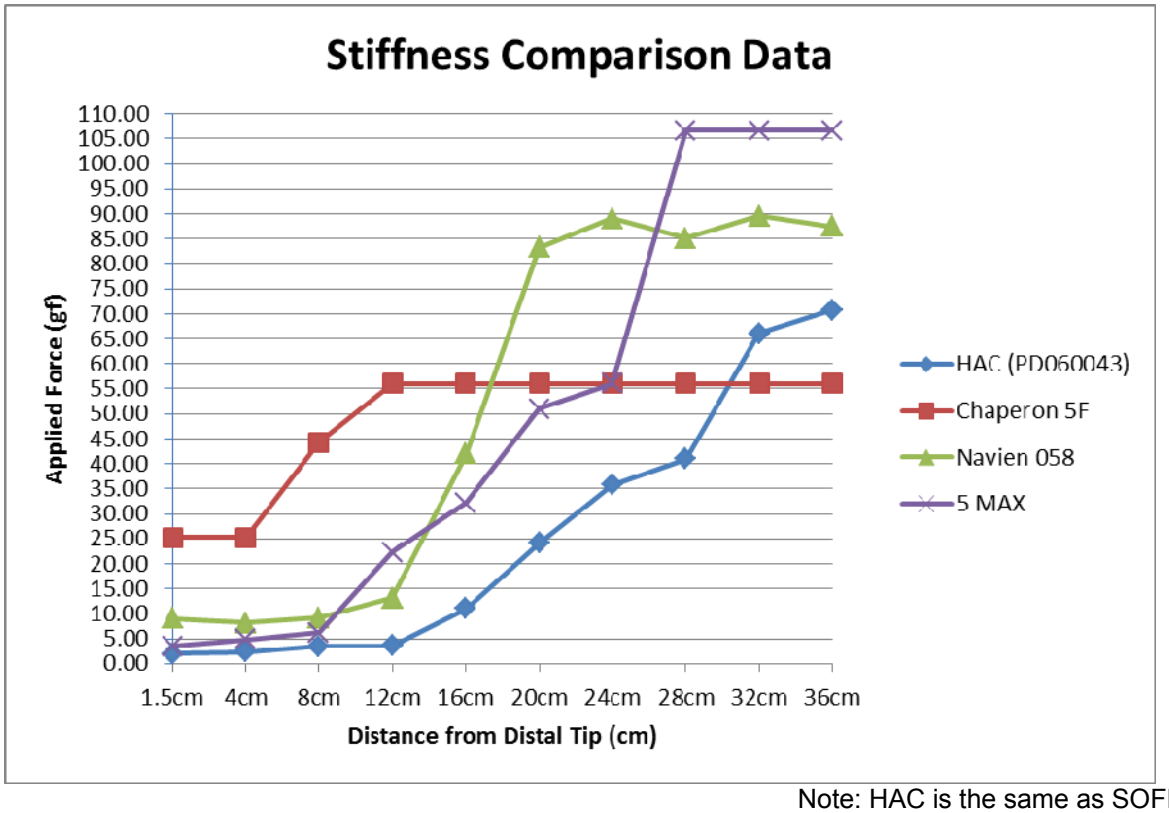
## 14.7. Catheter Stiffness

The purpose is to determine the stiffness, defined by applied load, of catheters in flexure at the bend point using an Instron Test Stand. This test provides a quantitative reference metric for evaluation of the catheter bending stiffness throughout its distal region which may influence its behavior while advancing to its target site.




Note: HAC is the same as SOFIA

## 14.8. Torque Strength Testing

The purpose of this test is to evaluate the torque strength of the catheter as defined by the number of turns to failure. The distal tip of the catheter is stabilized and the catheter is rotated in a single direction for up to 50 turns or until failure.

| | SOFIA N = 11 | Chaperon N = 3 | Navien/5 MAX N= 1 ea |
|---|---|---|---|
| # of rotations | 50 | 50 | 50 |
| Catheter breakage | No breaks | No breaks | No breaks |
| Acceptance Criteria | 50 rotations without catheter breakage or equivalent to competitive product catheters. | | |
| Pass/fail | Pass | | |

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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## 14.9. Catheter Flexural Fatigue

The purpose of this test method is to evaluate the catheter tensile strength and pressure characteristics after undergoing repeated fatigue cycles. This method covers two types of fatigue which the microcatheter is exposed to; 1- Flexural fatigue from repeated bending of the catheter during simulated use testing and 2- Flexural fatigue from repeated hoop stress on the catheter after pressure testing and air aspiration testing. This method combines many catheter test methods which stresses the catheter as summarized below:

**Catheter Flexural Fatigue**

| N = 22 | Simulated Use | Force at Break | Flow Rate | Static Burst Pressure | Catheter Leakage (liquid) |
|---|---|---|---|---|---|
| SOFIA | Pass | Pass | Pass | Pass | Pass |
| Specification | Pass required specified acceptance criteria after completing fatigue testing | | | | |

## 14.10. Surface Contamination

The purpose of the inspection is 1) to ensure the catheter surface is free from uncured hydrophilic coating. The surface must be free of visible functional or cosmetic defect attributable to the manufacturing, packaging and/or sterilization processes; 2) to ensure the distal tip is smooth, rounded and tapered; 3) to ensure integrity of catheter subsequently used for physical verification tests. Test Results are provided below:

**Surface Contamination**

| | N | Free from uncured coating | No surface particulate > .02 $mm^2$ | Free from surface defect | Embedded particulate = OD spec. | Distal Tip | PTFE Liner |
|---|---|---|---|---|---|---|---|
| SOFIA | 11 | Pass | Pass | Pass | Pass | Pass | Pass |

## 14.11. Force at Break

To determine the minimum force at break of the catheter shaft and hub-catheter connection is the objective of the test. Results are listed below:

**Force at Break for OD ≥ .045" (Distal) to < .072" (Hub)**

| N = 22 | Distal (lbf) | Hub (lbf) |
|---|---|---|
| Minimum | 5.92 (26.33) | 8.79 (39.10) |
| Maximum | 7.66 (34.07) | 14.02 (62.36) |
| Average | 7.09 (31.54) | 10.70 (47.60) |
| Std. Dev. | 0.41 (1.82) | 1.12 (4.98) |
| Acceptance Criteria | ≥ 2.25 lbf (10.01 N) | |
| Result | Pass | Pass |

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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## 14.12. Flow Rate

To measure the catheter injection flow rate of saline and/or contrast media as a function of the applied pressure is the purpose of this test. This test also evaluated and established the catheter compatibility with diagnostic agents (contrast media).

**Flow Rate (ml/sec)**

| SOFIA N=11 | Saline (100%) | | 50/50% contrast/saline | | 60/40% contrast/saline | | 76/24% contrast/saline | |
|---|---|---|---|---|---|---|---|---|
| | 100 psi | 300 psi | 100 psi | 300 psi | 100 psi | 300 psi | 100 psi | 300 psi |
| Minimum | 11.0 | 20.0 | 9.6 | 17.0 | 8.8 | 16.0 | 7.0 | 15.0 |
| Maximum | 15.0 | 22.0 | 11.0 | 19.0 | 11.0 | 18.0 | 8.6 | 17.0 |
| Average | 11.9 | 20.7 | 10.1 | 17.9 | 9.5 | 17.0 | 7.7 | 16.4 |
| Chaperon (Avg) | 13.7 | 25.0 | 13.7 | 22.3 | 12.0 | 21.7 | 10.7 | 21.3 |
| Navien (Avg) | | | | | | | 8.5 | 17.7 |
| 5 MAX (Avg) | | | | | | | 10.7 | 21.7 |
| Specification | Reference data for IFU | | | | | | | |

## 14.13. Static Burst Pressure

The purpose of the testing is to evaluate the fluid leakage and damage of pressurized catheter as outlined in the ISO 10555-1. The catheter is connected via a leak-proof connection to a syringe. A hydraulic pressure is applied to the hub assembly. The pressure is then measured after 2 seconds. Results are summarized below:

**Static Burst Strength**

| | SOFIA (6 mos) N = 11 | Chaperon N = 3 | Navien N = 3 | 5 MAX N = 3 |
|---|---|---|---|---|
| Minimum | 122 | 1300 | 1107 | 129 |
| Acceptance Criteria | ≥ 46 psi | | | |
| Result | Pass | N/A | N/A | N/A |

## 14.14. Freedom from Leakage – Liquid

The purpose of the test is to ensure the device does not leak under pressure of fluid per the ISO 10555-1 Annex C (Fluid). The formation of fluid droplets or presence of escaped fluid on the surface of the microcatheter shaft or any part of the hub connection due to intraluminal pressure is recorded under the test condition. Results are summarized below:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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**Freedom from Leakage – liquid low pressure - long duration (6 mos)**

| N = 11 | |
|---|---|
| Acceptance criteria | No liquid leaking from device at 46 psi for 30 seconds |
| Result | Pass |

## 14.15. Freedom from Leakage - Air

The purpose of the test is to ensure air does not leak into the device according to the ISO 10555-1 Annex D (Air). A 10cc syringe is filled with at least 10cc of boiled and cooled water is inserted and filled into the hub. Once a droplet is formed, the syringe volume is then adjusted according to the standard. The bubble formation after the first 5 seconds is then recorded. Results are summarized below:

**Freedom from Leakage – Air (6 mos)**

| N = 11 | |
|---|---|
| Acceptance criteria | No air leaking (at hub) into syringe for 15 seconds |
| Result | Pass |

## 14.16. Dynamic Burst Pressure

The purpose of this test is to determine the dynamic burst pressure of catheter which is the hydrostatic pressure at which a free-flowing catheter fails or ruptures. Total of 22 units of SOFIA were evaluated.

**Dynamic Burst Pressure (6 mos)**

| N = 22 | |
|---|---|
| Acceptance criteria | Microcatheter will not burst below 300 psi (2068kPa) |
| Result | Pass |

## 14.17. Particulate Measurement Analysis

As outlined in the USP <788>, analysis was performed to quantify particulate matter in injections of the SOFIA Catheter after advancement/retraction procedures.

The "particulate matter in injection" was performed by PMT (Particle Measurement Technology Co.), an independent laboratory per USP Section <788>. A total of 3 SOFIA were tested by automated light obscuration particle counter.

Samples were tested in the simulated intra-cranial silicon aneurysms tortuous flow model. Samples were prepared according to the IFU. The samples were subjected to worst-case anticipated clinical conditions by cycling (advancement and retraction) ten times. The

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sample flushes collecting particulates generated during tracking were then tested according to the USP <788>.

As documented in the PMT Particle Analysis Report (Appendix 6), the result meets the requirements of the particle test if the statistical particle count does not exceed 25 particles equal to or greater than 10 microns in size, and/or 3 particles equal to or greater than 25 microns in size.

**Particulate Analysis**

| | Particles/mL (Avg) | | Particles/Device (Total) | | Particles >70µm |
|---|---|---|---|---|---|
| | >10µm | > 25µm | >10µm | > 25µm | |
| **SOFIA** Sample #1 | 1.8 | 0.20 | 108 | 12 | No particles > 70 microns detected |
| Sample #2 | 1.2 | 0.30 | 72 | 18 | No particles > 70 microns detected |
| Sample #3 | 0.9 | 0.00 | 54 | 0 | No particles > 70 microns detected |
| **Chaperon** (N=1) | 2.8 | 0.40 | 168 | 24 | No particles > 70 microns detected |
| **Navien 058** | 1.6 | 0.20 | 96 | 12 | No particles > 70 microns detected |
| Acceptance Criteria | < 25 particles/mL (for >10 microns)<br>< 3 particles/mL (for > 25 microns) | | | | |
| Results | All units in test group met the criteria – PASS. | | | | |

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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## 15. Biocompatibility

A full panel of biocompatibility studies was performed on representative samples of the SOFIA Retrieval Device. The biological safety has been verified in accordance with the ISO10993-1, Biological Evaluation of Medical Devices by an independent laboratory, Toxikon, located in Bedford, Massachusetts. The table below summarizes the tests conducted and the results provide assurance that the device [classified as externally communicating, circulating blood, limited contact (≤24 hrs)] has a safe biocompatibility profile. The Toxikon reports are provided in Appendix 7.

**Biocompatibility Summary for SOFIA Distal Access Catheter**

| Test Method | Standard | Test Material | Sample Preparation | Results | Conclusion |
|---|---|---|---|---|---|
| **Cytotoxicity** | | | | | |
| L929 MEM Elution Test - ISO | ISO 10993-5 No deviations | Distal Access Catheter | Test material extracted at 37°C for 24 hrs in MEM (6cm$^2$/ ml) | Grade 0 to 1(no to slight reactivity) | Non-cytotoxic (b)(4) Confidential and Proprietary |
| **Sensitization** | | | | | |
| Kligman Maximization Test - ISO | ISO 10993-10 No deviations | Distal Access Catheter | Test material extracted with NaCl and cottonseed oil at 70°C for 24 hrs at ratio of 6cm$^2$/ mL. | Grade I: Weak allergic potential | Not significant (b)(4) Confidential and Proprietary Information |
| **Irritation** | | | | | |
| Intracutaneous Injection Test - ISO | ISO 10993-10 No deviations | Distal Access Catheter | Test material extracted with NaCl and cottonseed oil at 70°C for 24 hrs at ratio of 6cm$^2$/ mL. | Comparative between control and test article = 0 | Non-irritant (b)(4) Confidential and Proprietary |
| **Hemocompatibility** | | | | | |
| Hemolysis - Rabbit Blood ASTM (Direct and Indirect) | ISO 10993-4 No deviations | Distal Access Catheter | -Direct:Test material was added to PBS at 6 cm$^2$/mL -Indirect: Test material extracted in PBS at 70°C for 24 hrs. -Tests incubated with rabbit blood for 3 hrs at 37°C. | Hemolysis index: 0.13% (direct) and 0.0% (indirect) | Non-hemolytic (b)(4) Confidential and Proprietary |
| Unactivated Partial Thromboplastin Time Assay (Direct) | ISO 10993-4 No deviations | Distal Access Catheter | Human plasma exposed to test material (6 cm$^2$/ mL) incubated at 37 °C for 15 min. | Test article = 88.9-92.4 seconds (Avg) (Not statistically different from negative and untreated ) | No effect on coagulation (b)(4) Confidential and Proprietary Information |
| Complement Activation C3a and SC5b-9 | ISO 10993-4 No deviations | Distal Access Catheter | Test material exposed to human plasma at ratio of 6cm$^2$/ml at 37 °C for 90 min. | C3a and SC5b-9 levels ≤ negative and untreated controls | No effect on complement activation (b)(4) Confidential and Proprietary Information |
| Dog Thrombogenicity | ISO 10993-4 No deviations | Distal Access Catheter | Test article was surgically inserted into jugular vein for a period of 4 hours. | Grade (test art.) = 0 Grade (control) = 0 | Not significant, (b)(4) Confidential and Proprietary Information |

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| Test Method | Standard | Test Material | Sample Preparation | Results | Conclusion |
|---|---|---|---|---|---|
| **Systemic Toxicity** | | | | | |
| Systemic toxicity-ISO | ISO 10993-11 No deviations | Distal Access Catheter | Test material extracted with NaCl and cottonseed oil at 70°C for 24 hrs at ratio of 6cm$^2$/ ml. Extracts injected in albino mice and monitored at 24, 48, and 72 hrs. | No significantly greater biological reaction than control. | No reaction (b)(4) Confidential and Proprietary Information |
| Rabbit Pyrogen Test (material mediated) - ISO | ISO 10993-11 No deviations | Distal Access Catheter | Test material extracted with NaCl at 70°C for 24 hrs at ratio of 6cm$^2$/ ml. Extracts injected in rabbit and monitored for body temperature. | Temperature (max) increase was 0.3°C from baseline. | Non-pyrogenic (b)(4) Confidential and Proprietary Information |

## 16. Packaging and Sterilization

The packaging for the SOFIA Catheter is fundamentally unchanged from the Chaperon with the addition of a dispenser tube that holds the catheter in place on the packaging card. As a result of the change, we have validated the packaging configuration and the results are documented in TR 12-288 (see Appendix 6).

**Packaging Configuration**

| Packaging | Existing Chaperon | SOFIA Catheter |
|---|---|---|
| Material | 1. Packaging card: Polyethylene<br>2. Pouch: Tyvek<br>3. Carton Box: Bleached Sulfate | 1. Dispenser tube: HDPE<br>2. Packaging card: polyethylene<br>3. Pouch: Tyvek<br>4. Carton Box: Bleached Sulfate |
| Package Configuration | Catheter is placed on packaging card which is inserted into the pouch. The pouch is placed inside a carton box. | Catheter is place in a dispenser tube, placed on a packaging card that is then inserted into the pouch. Placed in carton box. |
| Method of Supplying | Sterile and single use. | Same |
| Method of Sterilization | Ethylene oxide | Same |

The SOFIA Distal Access Catheter is intended to be sold sterile, for single use only. The device is sterilized using 100% ethylene oxide (EO) gas in the same manner as our existing Headway microcatheters. Sterilization is performed by an outside contractor, (b)(4) Confidential and Proprietary Information (b)(4) Confidential and Proprietary Information

The validation and routine EO sterilization method of the SOFIA is in accordance with the requirement of the ANSI/AAMI/ISO11135-2007, Medical Devices - Validation and routine control of ethylene oxide sterilization, overkill method.

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| Sterilization Summary | |
|---|---|
| Sterility Validation Method. | ANSI/AAMI/ISO11135-2007, Medical Devices- Validation and routine control of ethylene oxide sterilization, overkill method. |
| EO Residuals | EO and ECH residuals are below the limits established by ISO 10993-7 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals. |
| Sterilization Method | 100% ethylene oxide gas |
| Sterility Assurance Level | (SAL) – $10^{-6}$ |
| Sterilization Location | (b)(4) Confidential and Proprietary Information |

## 17. Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the SOFIA Distal Access Catheter when compared with the predicate device: Chaperon Guiding Catheter (K082385).

The devices,

- have the same intended use,
- use the same operating principle,
- incorporate the same basic design,
- are packaged and sterilized using same material and processes.

In summary, the SOFIA Distal Access Catehter described in this submission is, in our opinion, substantially equivalent to the predicate devices.

## 18. ISO/EC Certification and Compliance

MicroVention develops and manufactures their products under its certified quality system (ISO13485:2003 +AC:2009, CMDCAS). All MicroVention products are developed and tested based upon design control procedures that include risk analysis, in vitro, in vivo and clinical studies (as appropriate). The MicroVention facility is US FDA registered as well as licensed by the California State Department of Health.

Copy of the MicroVention ISO 13485 Certificate is provided in the Appendix 8.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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# 19. List of Appendices

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| **Appendix 2 .....** | Product Drawing |
| **Appendix 3 .....** | QP 4.1, Design and Development Quality Procedure |
| **Appendix 4 .....** | QP 4.8, Risk Management Quality Procedure |
| **Appendix 5 .....** | RA 060004, Risk Assessment and Control Analysis<br>FA060010, dFMEA |
| **Appendix 6 .....** | TP/TR 12-280, Design Verification and Validation, Protocol and Report (with 6 month accelerated aging)<br>TR12-288, Packaging Validation |
| **Appendix 7 .....** | Biocompatibility Reports (Toxikon) |
| **Appendix 8 .....** | MicroVention ISO Certificate |

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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# Appendix 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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# SOFIA™ Distal Access Catheter

## Instructions for Use

Carefully read all instructions prior to use.

### DEVICE DESCRIPTION

The SOFIA™ Distal Access Catheter is a non-tapered, single-lumen, flexible catheter equipped with the coil and the braid reinforcement. The distal segment is steam-shapeable to facilitate vessel selection and also has a hydrophilic coating for navigation through the vasculatures. The radiopaque marker is located at the distal end of the catheter for visualization under fluoroscopy.

### CONTENTS

One Distal Access Catheter
One Introducer Sheath
One Shaping Mandrel

### INDICATIONS FOR USE

The SOFIA™ Distal Access Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA™ Distal Access Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. The SOFIA™ Distal Access Catheter is not intended for use in coronary arteries.

### CONTRAINDICATIONS

There are no known contraindications.

### CAUTION

**Rx Only**: Federal (USA) law restricts this device to sale by or on the order of a physician.

Do not use if pouch is opened or damaged.

This device is intended for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose in accordance with hospital, administrative and/or local government policy.

### WARNINGS

The SOFIA™ Distal Access Catheter should only be used by physicians who have received appropriate training in interventional techniques.

The SOFIA™ Distal Access Catheter is provided sterile and non-pyrogenic. Do not use if the packaging is breached or damaged.

Inspect the SOFIA™ Distal Access Catheter prior to use. Do not use the device if any damages or irregularities are observed.

Appropriate anti-coagulation and anti-platelet therapy should be administered per standard medical practice.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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The SOFIA™ Distal Access Catheter should be manipulated under fluoroscopic guidance. Do not advance or withdraw the device when excessive resistance is met until the cause of resistance is determined.

Do not use the SOFIA™ Distal Access Catheter with Ethiodol or Lipiodol contrast media or other such contrast media which includes the components of those agents.

Do not use organic solvents as the device may be damaged.

Do not exceed 2070 kPa (300 psi) maximum recommended infusion pressure. Excess pressure may damage the device or injure the patient. Carefully monitor placement of the distal tip when using a power injector to infuse.

Do not make more than 90 degree angle on the Shaping Mandrel. Steaming of the distal tip with more than 90 degree angle may result in damage to the device.

Do not repeat steaming of the same device more than once, which may result in damage to the device.

Torquing the SOFIA™ Distal Access Catheter excessively while kinked may damage the device resulting in separation of the device. Withdraw the entire device (the device, microcatheter, and guidewire) if the device is severely kinked.

The Introducer Sheath is not intended for use inside the patient body. Ensure that the Introducer Sheath is removed from the SOFIA™ Distal Access Catheter once the distal shaft of the SOFIA™ Distal Access Catheter is placed inside the patient body.

**PRECAUTIONS**

Exercise care in handling the SOFIA™ Distal Access Catheter to reduce the chance of accidental damage.

Verify compatibility of the SOFIA™ Distal Access Catheter when using other ancillary devices commonly used in intravascular procedures. The physician must be familiar with percutaneous, intravascular techniques and possible complications associated with the procedure.

Use caution when manipulating the SOFIA™ Distal Access Catheter in tortuous vasculature to avoid damage. Avoid advancing or withdrawal against resistance until the cause of resistance is determined.

Presence of calcifications, irregularities, or other devices may damage the SOFIA™ Distal Access Catheter and potentially affect its insertion or removal.

Maintain perfusion of heparinized saline for inner lumen of the SOFIA™ Distal Access Catheter to prevent thrombus formation.

The hydrophilic coating on the SOFIA™ Distal Access Catheter should be hydrated with heparinized saline before use. Keep the coating hydrated and do not allow the coating to dry.

**POTENTIAL COMPLICATIONS**

Potential complications include, but are not limited to: vessel or aneurysm perforation, vasospasm, hematoma at the site of entry, embolism, ischemia, intracerebral/intracranial hemorrhage, pseudo aneurysm, seizure, stroke, infection, vessel dissection, thrombus formation, and death.

**COMPATIBILITY**

Refer to product label for device dimensions. Use the information on labeling provided with other devices to determine device compatibility.

**PREPARATION FOR USE**

1. Carefully remove the SOFIA™ Distal Access Catheter and the Introducer Sheath from the package.



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2. Inspect the SOFIA™ Distal Access Catheter for any damage.
   **WARNING**: Do not use the device if any damages or irregularities are observed.

   If steam shaping is desired, use the technique outlined in the step 3. Otherwise proceed to the step 4.

3. **STEAM SHAPING**
   a. Bend the Shaping Mandrel for desired shape.
      **WARNING**: Do not make more than 90 degree angle on the Shaping Mandrel. Steaming of the distal tip with more than 90 degree angle may result in damage to the device.
   b. Carefully insert the Shaping Mandrel into the distal tip of the SOFIA™ Distal Access Catheter.
   c. Hold the distal segment together with the Shaping Mandrel and steam it for 30 seconds.
   d. Immediately place the shaped distal segment into heparinized saline to set the shape.
   e. Inspect the distal shaft for any damage.
      **WARNING**: Do not use the device if any damages or irregularities are observed.
   f. Remove the Shaping Mandrel from the SOFIA™ Distal Access Catheter.
      Do not use the device if any damages or irregularities are observed.
      **WARNING**: Do not repeat steaming of the same device more than once, which may result in damage to the device.

4. Flush the lumen of the SOFIA™ Distal Access Catheter with heparinized saline. Attach a rotating hemostatic valve (RHV) to the proximal hub of the SOFIA™ Distal Access Catheter. Set up the line for perfusion of heparinized saline through the sidearm of the RHV.

5. Hydrate the hydrophilic coating on the SOFIA™ Distal Access Catheter with heparinized saline before use. Keep the coating hydrated and do not allow the coating to dry.

**DELIVERY OF THE HYBRID DISTAL ACCESS CATHETER**

6. Go to the step 7 or 8, depending on the situation described below and choose appropriate devices for navigation of the SOFIA™ Distal Access Catheter.

7. **Navigation through the vasculature, except for the intracranial vasculature**
   a. Prepare 0.035” or 0.038” Guidewire for navigation of the SOFIA™ Distal Access Catheter.
   b. Insert the guidewire into the SOFIA™ Distal Access Catheter and advance the Guidewire until the Guidewire and the SOFIA™ Distal Access Catheter are aligned at the distal end.
   c. Using the Introducer Sheath provided in the package, carefully insert the SOFIA™ Distal Access Catheter and the Guidewire through a hemostatic valve of the femoral sheath
   d. Remove the Introducer Sheath from the SOFIA™ Distal Access Catheter once the distal shaft of the SOFIA™ Distal Access Catheter is placed inside the patient body.
      **WARNING:** Introducer Sheath is not intended for use inside the patient body.
   e. Under fluoroscopic guidance, advance or withdraw the SOFIA™ Distal Access Catheter over the guidewire until desired position is attained or before the intracranial position is achieved. Select vessels by slowly torqueing the SOFIA™ Distal Access Catheter if necessary.
      **WARNING**: Do not advance or withdraw the device when excessive resistance is met until the cause of resistance is determined.
      **WARNING**: Torqueing the SOFIA™ Distal Access Catheter excessively while kinked may damage the device resulting in separation of the device. Withdraw the entire device (the device, Microcatheter, and Guidewire) if the device is severely kinked.
      **WARNING**: Do not exceed 2070 kPa (300 psi) maximum recommended infusion pressure. Excess pressure may damage the device or injure the patient. Carefully monitor placement of the distal tip when using a power injector to infuse.
   f. Go to the step 8 for navigation through the intracranial vasculatures. Otherwise proceed to the step 9.

8. **Navigation through the intracranial vasculature**
   a. Prepare Microcatheter and compatible Guidewire for navigation of the SOFIA™ Distal Access Catheter.
   b. Slowly remove, if any, devices previously inserted in the SOFIA™ Distal Access Catheter. Insert the Microcatheter with the Guidewire into the SOFIA™ Distal Access Catheter.



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c. Under fluoroscopic guidance, advance or withdraw the SOFIA™ Distal Access Catheter over the Microcatheter and the Guidewire until desired position is attained. Select vessels by slowly torqueing the SOFIA™ Distal Access Catheter if necessary.
**WARNING**: Do not advance or withdraw the device when excessive resistance is met until the cause of resistance is determined.
**WARNING**: Torqueing the SOFIA™ Distal Distal Access Catheter excessively while kinked may damage the device resulting in separation of the device. Withdraw the entire device (the device, Microcatheter, and Guidewire) if the device is severely kinked.
**WARNING**: Do not exceed 2070 kPa (300 psi) maximum recommended infusion pressure. Excess pressure may damage the device or injure the patient. Carefully monitor placement of the distal tip when using a power injector to infuse.

9. Slowly remove the Guidewire or the Microcatheter if necessary. Make sure that continuous perfusion of heparinized saline is maintained through the sidearm of the RHV.
**NOTE:** The Microcatheter used to navigate the SOFIA™ Distal Access Catheter may be kept for the rest of procedure.

The physician has the discretion to modify described manipulations of the SOFIA™ Distal Access Catheter to accommodate the complexity and variation in procedures. Any technique modification must be consistent with previously described instructions, warnings, precautions and patient safety information.

**STORAGE**

Avoid exposure to water, sunlight, extreme temperatures and high humidity during storage. Store the SOFIA™ Distal Access Catheter under controlled room temperature. See the product label for the device shelf life. Do not use the device beyond the labeled shelf life.

**MATERIALS**

The SOFIA™ Distal Access Catheter does not contain latex or PVC materials.

**SYMBOLS**

| | | | |
|---|---|---|---|
| LOT | Lot Number | | Do Not Reuse |
| REF | Catalog Number | | Attention, Consult Accompanying Documents |
| CONT | Contents | | Use by Date |
| STERILE EO | Sterilized Using Ethylene Oxide | | Date of Manufacture |
| CE | CE Mark | | Manufacturer |
| EC REP | Authorized European Representative | | Non-pyrogenic |

**WARRANTY**
MicroVention, Inc. warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling, storage, cleaning and sterilization of the device as well as factors relating to the patient, diagnosis, treatment, surgical procedure and other matters beyond MicroVention's control directly affect the device and the results obtained from its use. MicroVention's obligation under this warranty is limited to the repair or replacement of this device and MicroVention shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this device. MicroVention neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. MicroVention assumes no liability with respect to devices reused, reprocessed or resterilized and makes no warranties, expressed or implied, including, but not limited to, merchantability or fitness for intended use, with respect to such device.
Prices, specifications and model availability are subject to change without notice.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Tel: (714) 247-8000

www.microvention.com

CE 0297

EC REP

**Authorized European Representative:**
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78100 Saint-Germain-en-Laye
France
Tel: +33 (0)1 39 21 77 46
Fax: +33 (0)1 39 21 16 01

PD110436 Rev. A
2013-2

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5F **SOFIA**

**125 cm / STR**

REF "Catalog No."
Use By YYYY-MM

"One Long Bar Code with Bc1 and BC2 information"

# SOFIA Distal Access Catheter

MicroVention® TERUMO

**Distal Access Catheter**

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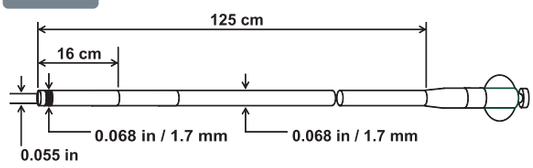


**Straight Shapeable**

REF Catalog Number

**DA5125ST**

LOT Lot Number

**"Lot No."**

"Bar Code 1"
**REF: "Catalog No."**
"Bar Code 2"
**LOT NO: "Lot No."**

SOFIA
Distal Access Catheter
125 cm / STR

"Bar Code 1"
**REF: "Catalog No."**
"Bar Code 2"
**LOT NO: "Lot No."**

SOFIA
Distal Access Catheter
125 cm / STR

"Bar Code 1"
**REF: "Catalog No."**
"Bar Code 2"
**LOT NO: "Lot No."**

SOFIA
Distal Access Catheter
125 cm / STR

STERILE EO

Do Not Reuse.

Attention: Refer to Instructions For Use.

Rx-ONLY

Non-pyrogenic

**MicroVention, Inc.**
1311 Valencia Avenue
Tustin, CA 92780 USA
PH: 714.247.8000
www.microvention.com

EC REP **MicroVention Europe**
30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France

CONT Contents
**1** Distal Access Catheter
**1** Introducer Sheath
**1** Shaping Mandrel

LOT "XXXXXXXX"

Date of Manufacture YYYY-MM

CE 0297
Made in U.S.A.

Use By YYYY-MM

EDXXXX-XXX

LB11192A-DRAFT

AW11020 Rev. A 2013-04 (LB11190)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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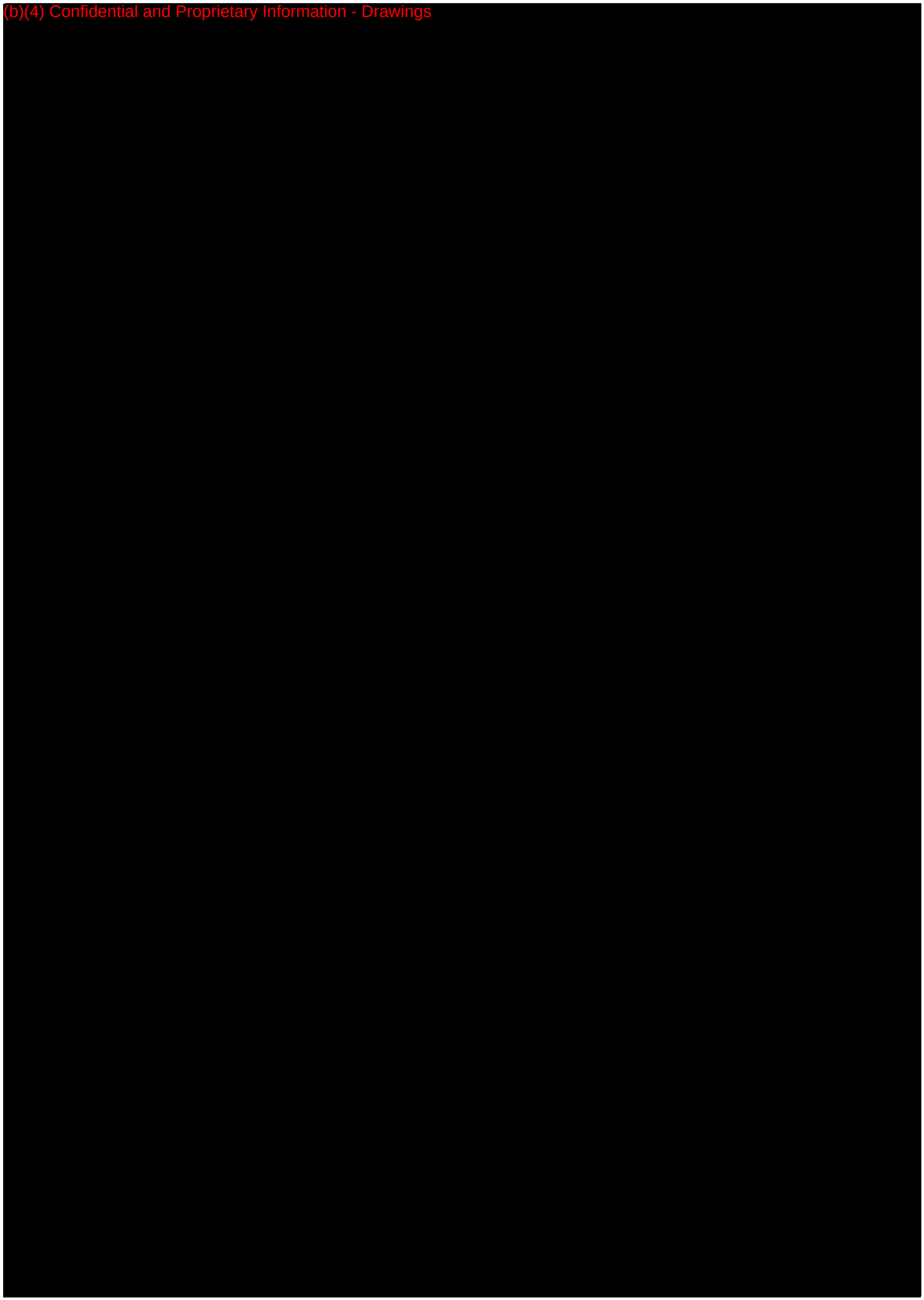
# Appendix 2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.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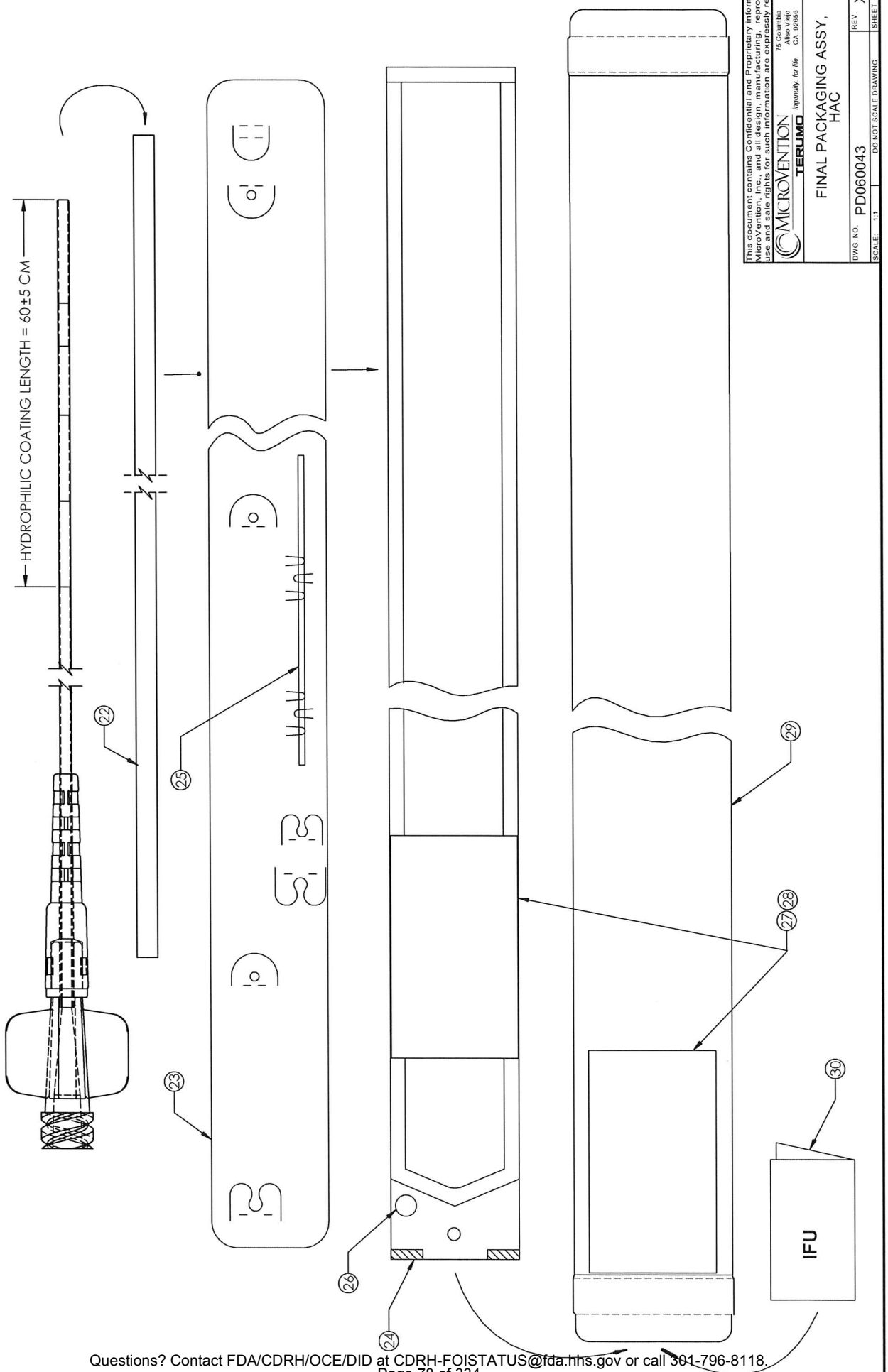


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MICROVENTION TERUMO ingenuity for life
75 Columbia Aliso Viejo CA 92656

FINAL PACKAGING ASSY, HAC

DWG. NO. PD060043 REV. X23

SCALE: 1:1 DO NOT SCALE DRAWING SHEET 2 of 2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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# Appendix 3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information - Quality Assurance Procedure

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# Appendix 5

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information - Risk Assessment and Risk Control Analysis

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# Appendix 6

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information - Test Protocol

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# Appendix 7

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.


# Appendix 8

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

# CERTIFICATE

This is to certify that the company

## MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA 92780
United States of America

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:
Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, and Intravascular Access Devices and Accessories, Clot and Foreign Body Retrieval Devices

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

## EN ISO 13485 : 2003 + AC : 2009

| | |
|---|---|
| Certificate registration No. | 411133 MP29 |
| Certificate unique ID | 170555867 |
| Effective date | 2012-10-12 |
| Expiry date | 2014-10-31 |
| Frankfurt am Main | 2012-10-12 |

DAkkS Deutsche Akkreditierungsstelle D-ZM-16021-01-01

**DQS Medizinprodukte GmbH**

Frank Graichen
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

Member of IQNet THE INTERNATIONAL CERTIFICATION NETWORK

Confidential

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

August-Schanz-Straße 21, 60433 Frankfurt am Main, Tel. +49 (0) 69 95427-263, medical.devices@dqs.de


20120903/3/EN380307

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

# Annex to Certificate
# Certificate registration No.: 411133 MP29
# Certificate unique ID: 170555867
# Effective date: 2012-10-12

## MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA 92780
United States of America

| Location | Scope |
|---|---|
| MicroVention, Inc.<br>1311 Valencia Ave.<br>Tustin, CA 92780<br>United States of America | Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, and Intravascular Access Devices and Accessories, Clot and Foreign Body Retrieval Devices |
| MicroVention, Inc.<br>Production Site<br>75 Columbia<br>Aliso Viejo, CA 92656<br>United States of America | Manufacturing of Embolization Prostheses and Accessories, and Intravascular Access Devices and Accessories, Clot and Foreign Body Retrieval Devices |
| MicroVention Costa Rica, S.R.L.<br>Production Site<br>Zona Franca Coyol<br>Alajuela<br>Costa Rica | Manufacturing of Embolization Prostheses and Accessories, and Intravascular Access Devices and Accessories, Clot and Foreign Body Retrieval Devices |
| MicroVention, Inc.<br>Distribution Site<br>1800 E. Wilshire Ave.<br>Santa Ana 92705<br>United States of America | Distribution of Embolization Prostheses and Accessories, and Intravascular Access Devices and Accessories, Clot and Foreign Body Retrieval Devices |


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

# EC Design-Examination Certificate

## DQS GmbH

**Deutsche Gesellschaft zur Zertifizierung von Managementsystemen**

hereby certifies to the manufacturer

## MicroVention Inc.

1311 Valencia Ave.
Tustin, CA 92780
United States of America

that following product

## Chaperon Guiding Catheter System

is conform to the

## essential requirements of Annex I of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

**Examination Basis:** Chaperon Dossier Summary_2008-Sep-14.pdf
The further examination basis is detailed in the following named report and the relating documents.

**Examination reports:** Report Design Examination Chaperon Rev 2008-09-14.doc 07/2008

The results of the examination are detailed in the above mentioned report(s) and the therein named relating documents.

**Validity:** This EC Design-Examination Certificate is based on section 4 of Annex II of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and is only valid in connection with the valid DQS Certificate No.: 411133 MR2 according to Annex II of the Council Directive 93/42/EEC. Changes to the approved design must receive further approval from the notified body.

| | |
|---|---|
| This certificate is valid until | 2013-10-22 |
| Certificate Registration No. | 428948 MRA |
| Frankfurt am Main | 2009-07-21 |

Ass. iur. M. Drechsel

Dipl.-Bw. J. Böge

MANAGING DIRECTORS
D-60433 Frankfurt am Main, August-Schanz-Straße 21

Number of DQS as notified body according to Council Directive 93/42EWG: 0297


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

## Napperli, Jesse *

**From:** Napperli, Jesse *
**Sent:** Monday, November 25, 2013 4:24 PM
**To:** 'NAOMI.GONG@MICROVENTION.COM'
**Cc:** DCCLetters
**Subject:** K131482 SE LETTER
**Attachments:** K131482.pdf


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

S

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

# COVER SHEET MEMORANDUM

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics and
Radiological Health

**From:** Reviewer Name Samuel K. Shimp III

**Subject:** 510(k) Number K131482

**To:** The Record

**Please list CTS decision code:** SE - Substantially Equivalent

☐ Refused to Accept (Note: this is considered the first review cycle. See screening checklist.)

☐ Hold (Additional Information or Telephone Hold)

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

| Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.) | YES | NO |
|---|---|---|
| Indications for Use Page *(Attach IFU)* | X | |
| 510(k) Summary or 510(k) Statement *(Attach Summary or Statement)* | X | |
| Truthful and Accurate Statement *(Must be present for a Final Decision)* | X | |
| Is the device Class III? | | X |
| Does firm reference standards? (If yes, please attach Form 3654.) | X | |
| Is this a combination product? | | X |
| Is this a reprocessed single use device? (See Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices.) | | X |
| Is this device intended for pediatric use only? | | X |
| Is this a prescription device? (If both prescription & OTC, check both boxes.) | X | |
| Is clinical data necessary to support the review of this 510(k)? | | X |
| For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.) | | X |
| Does this device include an Animal Tissue Source? | | X |
| All Pediatric Patients age <= 21 | | X |
| Neonate/Newborn (Birth to 28 days) | | X |
| Infant (29 days to < 2 years) | | X |
| Child (2 years to <12 years) | | X |
| Adolescent (12 years to <18 years) | | X |
| Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or tesating, different protocol procedures, etc.) | | X |
| Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years) | | X |

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

| | | |
|---|---|---|
| Nanotechnology | | X |
| Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance) | | X |

| | |
|---|---|
| **Regulation Number:** | 870.1250 |
| **Class:** | II |
| **Product Code:** | DQY |
| **Additional Product Codes:** | DQO |

**Digital Signature Concurrence Table**
**(Not all signatures may be required)**

| | |
|---|---|
| Branch Chief Sign-Off | Quynh T. Hoang -S<br>2013.11.21 18:25:48 -05'00' |
| Division Sign-Off | Joyce M. Whang -S<br>2013.11.22 12:17:40 -05'00' |

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

K131482-3001

MicroVention
TERUMO

FDA CDRH DMC
JUN 12 2013
Received

June 10, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Health
IDE Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: K131482 RTA1 Response
For SOFIA Catheter

Dear Dr. Shimp:

This is submitted in response to RTA notification (dated June 7, 2013) for the Special 510(k) for the SOFIA Catheter.

An eCopy can be found on the included CD and it is an exact duplicate of the paper copy. Please contact me if additional information is needed.

***Statement of Confidentiality:*** *MicroVention, Inc. considers the information in this submission to be confidential information. We ask that this proprietary information herein be treated as confidential in accordance with the Freedom of Information Act.*

Sincerely,

Naomi Gong 6-11-2013

Naomi Gong
Regulatory Affairs Project Manager
MicroVention, Inc.
Ph: 714-247-8055
Fx: 714-247-8014
naomi.gong@microvention.com



Confidential Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.



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Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

K131482/S1

MicroVention
TERUMO

June 10, 2013

FDA CDRH DMC
JUN 11 2013
Received

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Regulatory Affairs Project Manager
MicroVention, Inc.
Ph: 714-247-8055
Fx: 714-247-8014
naomi.gong@microvention.com


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18

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

June 10, 2013

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Sincerely,

Naomi Gong
Regulatory Affairs Project Manager
MicroVention, Inc.
Ph: 714-247-8055
Fx: 714-247-8014
naomi.gong@microvention.com


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.


From the Elements of a Complete Submission (RTA Items), please see our responses to the identified items noted by the FDA reviewer:

**Section 8a** –

FDA Comments: The submission does not state whether or not there were prior submissions. Section F of form 3514 was left blank which is not adequate for declaring that there were no prior submissions. You need to provide a statement declaring whether or not there were prior submissions related to the subject device.

MicroVention Response: An updated Form-3514 is included with Section F completed is provided in Appendix A.

**Section 18a** – Proposed Labeling, all changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.

FDA Comments: Only a clean copy of the labeling is provided. The labeling provided does not identify any changes from the previous version of the labeling. There is no narrative description or highlighted/redlined version of the labeling to prominently identify the proposed labeling changes.

MicroVention Response: A copy of the proposed IFU with highlighted (in yellow) changes resulting from device modification(s) is provided in Appendix B.

---

This information should fulfill the elements outlined in the administrative review of a Special 510(k) and remove the current RTA hold status of the submission.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.


# Appendix A

Records Processed Under FDA Request #2015-6024; Released by CDRH on 09-26-2016.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

# CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

| Date of Submission | User Fee Payment ID Number | FDA Submission Document Number *(if known)* |
|---|---|---|
| 05/21/2013 | (b) (4) | |

## SECTION A TYPE OF SUBMISSION

| PMA | PMA & HDE Supplement | PDP | 510(k) | Request for Feedback |
|---|---|---|---|---|
| ☐ Original Submission | ☐ Regular (180 day) | ☐ Original PDP | ☒ Original Submission: | ☐ Pre-Submission |
| ☐ Premarket Report | ☐ Special | ☐ Notice of Completion | ☐ Traditional | ☐ Informational Meeting |
| ☐ Modular Submission | ☐ Panel Track (PMA Only) | ☐ Amendment to PDP | ☒ Special | ☐ Submision Issue Meeting |
| ☐ Amendment | ☐ 30-day Supplement | | ☐ Abbreviated (Complete section I, Page 5) | ☐ Day 100 Meeting |
| ☐ Report | ☐ 30-day Notice | | ☐ Additional Information | ☐ Agreement Meeting |
| ☐ Report Amendment | ☐ 135-day Supplement | | ☐ Third Party | ☐ Determination Meeting |
| ☐ Licensing Agreement | ☐ Real-time Review | | | ☐ Study Risk Determination |
| | ☐ Amendment to PMA & HDE Supplement | | | ☐ Other *(specify):* |
| | ☐ Other | | | |

| IDE | Humanitarian Device Exemption (HDE) | Class II Exemption Petition | Evaluation of Automatic Class III Designation (De Novo) | Other Submission |
|---|---|---|---|---|
| ☐ Original Submission | ☐ Original Submission | ☐ Original Submission | ☐ Original Submission | ☐ 513(g) |
| ☐ Amendment | ☐ Amendment | ☐ Additional Information | ☐ Additional Information | ☐ Other *(describe submission):* |
| ☐ Supplement | ☐ Supplement | | | |
| | ☐ Report | | | |
| | ☐ Report Amendment | | | |

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

## SECTION B SUBMITTER, APPLICANT OR SPONSOR

| Company / Institution Name | Establishment Registration Number *(if known)* | | |
|---|---|---|---|
| MicroVention, Inc. | 2032493 | | |
| Division Name *(if applicable)* | Phone Number *(including area code)* | | |
| | 714-247-8055 | | |
| Street Address | FAX Number *(including area code)* | | |
| 1311 Valencia Avenue | 714-247-8014 | | |
| City | State / Province | ZIP/Postal Code | Country |
| Tustin | CA | 92780 | USA |
| Contact Name | | | |
| Naomi Gong | | | |
| Contact Title | Contact E-mail Address | | |
| Sr. Regulatory Affairs Project Manager | naomi.gong@microvention.com | | |

## SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

| Company / Institution Name | | | |
|---|---|---|---|
| | | | |
| Division Name *(if applicable)* | Phone Number *(including area code)* | | |
| | | | |
| Street Address | FAX Number *(including area code)* | | |
| | | | |
| City | State / Province | ZIP Code | Country |
| | | | |
| Contact Name | | | |
| | | | |
| Contact Title | Contact E-mail Address | | |
| | | | |

## SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

☐ Other Reason *(specify):*

## SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

☐ Other Reason *(specify):*

## SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

☒ Other Reason *(specify):*

Catheter is similar to predicate device with same intended use (indications for use)

## SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 1 | DQY | 2 | | 3 | | 4 | |
| 5 | | 6 | | 7 | | 8 | |

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

| | *510(k) Number* | | *Trade or Proprietary or Model Name* | | *Manufacturer* |
|---|---|---|---|---|---|
| 1 | K082385 | 1 | Chaperon Guiding Catheter | 1 | MicroVention, Inc.<br>1311 Valencia Avenue, Tustin, CA 92780 |
| 2 | | 2 | | 2 | |
| 3 | | 3 | | 3 | |
| 4 | | 4 | | 4 | |
| 5 | | 5 | | 5 | |
| 6 | | 6 | | 6 | |

## SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Percutaneous catheter

| | Trade or Proprietary or Model Name for This Device | | Model Number |
|---|---|---|---|
| 1 | SOFIA Distal Access Catheter | 1 | DA5125ST |
| 2 | | 2 | |
| 3 | | 3 | |
| 4 | | 4 | |
| 5 | | 5 | |

FDA document numbers of all prior related submissions *(regardless of outcome)*

| | | | | | |
|---|---|---|---|---|---|
| 1 None | 2 | 3 | 4 | 5 | 6 |
| 7 | 8 | 9 | 10 | 11 | 12 |

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

## SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

| Product Code | C.F.R. Section *(if applicable)* | Device Class |
|---|---|---|
| DQY | 21 CFR 870.1250 | ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified |

Classification Panel

Cardiovascular Devices

Indications *(from labeling)*

The SOFIA Distal Access Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries.

Records processed under FOIA Request #2015-6024, Released by CDRH on 09-26-2016.

| ***Note:*** Submission of the information entered in Section H does not affect the need to submit device establishment registration. | FDA Document Number *(if known)* |
|---|---|

## SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

| ☒ Original ☐ Add ☐ Delete | Facility Establishment Identifier (FEI) Number: 2032493 | ☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler |
|---|---|---|

| Company / Institution Name | Establishment Registration Number | | |
|---|---|---|---|
| MicroVention, Inc. | 2032493 | | |
| **Division Name *(if applicable)*** | **Phone Number *(including area code)*** | | |
| | 714-247-8000 | | |
| **Street Address** | **FAX Number *(including area code)*** | | |
| 1311 Valencia Avenue | 714-247-8005 | | |
| **City** | **State / Province** | **ZIP Code** | **Country** |
| Tustin | CA | 92780 | USA |

| Contact Name | Contact Title | Contact E-mail Address |
|---|---|---|
| Naomi Gong | Sr. RA Project Manager | naomi.gong@microvention.com |

| ☒ Original ☐ Add ☐ Delete | Facility Establishment Identifier (FEI) Number: | ☐ Manufacturer ☒ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler |
|---|---|---|

| Company / Institution Name | Establishment Registration Number | | |
|---|---|---|---|
| Sterigenics | 2011171 | | |
| **Division Name *(if applicable)*** | **Phone Number *(including area code)*** | | |
| | 951-340-0700 | | |
| **Street Address** | **FAX Number *(including area code)*** | | |
| 4900 South Griffith Avenue | | | |
| **City** | **State / Province** | **ZIP Code** | **Country** |
| Los Angeles | CA | 90058 | USA |

| Contact Name | Contact Title | Contact E-mail Address |
|---|---|---|
| Sharon Huges | Representative | losangelessales@sterigenics.com |

| ☐ Original ☐ Add ☐ Delete | Facility Establishment Identifier (FEI) Number: | ☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler |
|---|---|---|

| Company / Institution Name | Establishment Registration Number | | |
|---|---|---|---|
| | | | |
| **Division Name *(if applicable)*** | **Phone Number *(including area code)*** | | |
| | | | |
| **Street Address** | **FAX Number *(including area code)*** | | |
| | | | |
| **City** | **State / Province** | **ZIP Code** | **Country** |
| | | | |

| Contact Name | Contact Title | Contact E-mail Address |
|---|---|---|
| | | |

## SECTION I UTILIZATION OF STANDARDS

**Note:** Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

| | Standards No. | Standards Organization | Standards Title | Version | Date |
|---|---|---|---|---|---|
| **1** | | | | | |
| **2** | Standards No. | Standards Organization | Standards Title | Version | Date |
| **3** | Standards No. | Standards Organization | Standards Title | Version | Date |
| **4** | Standards No. | Standards Organization | Standards Title | Version | Date |
| **5** | Standards No. | Standards Organization | Standards Title | Version | Date |
| **6** | Standards No. | Standards Organization | Standards Title | Version | Date |
| **7** | Standards No. | Standards Organization | Standards Title | Version | Date |

**Please include any additional standards to be cited on a separate page.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.*

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.


# Appendix B

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

# SOFIA™ Distal Access Catheter

## Instructions for Use

Carefully read all instructions prior to use.

### DEVICE DESCRIPTION

The SOFIA™ Distal Access Catheter is a non-tapered, single-lumen, flexible catheter equipped with the coil and the braid reinforcement. The distal segment is steam-shapeable to facilitate vessel selection and also has a hydrophilic coating for navigation through the vasculatures. The radiopaque marker is located at the distal end of the catheter for visualization under fluoroscopy.

### CONTENTS

One Distal Access Catheter
One Introducer Sheath
One Shaping Mandrel

### INDICATIONS FOR USE

The SOFIA™ Distal Access Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA™ Distal Access Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. The SOFIA™ Distal Access Catheter is not intended for use in coronary arteries.

### CONTRAINDICATIONS

There are no known contraindications.

### CAUTION

**Rx Only**: Federal (USA) law restricts this device to sale by or on the order of a physician.

Do not use if pouch is opened or damaged.

This device is intended for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose in accordance with hospital, administrative and/or local government policy.

### WARNINGS

The SOFIA™ Distal Access Catheter should only be used by physicians who have received appropriate training in interventional techniques.

The SOFIA™ Distal Access Catheter is provided sterile and non-pyrogenic. Do not use if the packaging is breached or damaged.

Inspect the SOFIA™ Distal Access Catheter prior to use. Do not use the device if any damages or irregularities are observed.

Appropriate anti-coagulation and anti-platelet therapy should be administered per standard medical practice.



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The SOFIA™ Distal Access Catheter should be manipulated under fluoroscopic guidance. Do not advance or withdraw the device when excessive resistance is met until the cause of resistance is determined.

Do not use the SOFIA™ Distal Access Catheter with Ethiodol or Lipiodol contrast media or other such contrast media which includes the components of those agents.

Do not use organic solvents as the device may be damaged.

Do not exceed 2070 kPa (300 psi) maximum recommended infusion pressure. Excess pressure may damage the device or injure the patient. Carefully monitor placement of the distal tip when using a power injector to infuse.

Do not make more than 90 degree angle on the Shaping Mandrel. Steaming of the distal tip with more than 90 degree angle may result in damage to the device.

Do not repeat steaming of the same device more than once, which may result in damage to the device.

Torquing the SOFIA™ Distal Access Catheter excessively while kinked may damage the device resulting in separation of the device. Withdraw the entire device (the device, microcatheter, and guidewire) if the device is severely kinked.

The Introducer Sheath is not intended for use inside the patient body. Ensure that the Introducer Sheath is removed from the SOFIA™ Distal Access Catheter once the distal shaft of the SOFIA™ Distal Access Catheter is placed inside the patient body.

**PRECAUTIONS**

Exercise care in handling the SOFIA™ Distal Access Catheter to reduce the chance of accidental damage.

Verify compatibility of the SOFIA™ Distal Access Catheter when using other ancillary devices commonly used in intravascular procedures. The physician must be familiar with percutaneous, intravascular techniques and possible complications associated with the procedure.

Use caution when manipulating the SOFIA™ Distal Access Catheter in tortuous vasculature to avoid damage. Avoid advancing or withdrawal against resistance until the cause of resistance is determined.

Presence of calcifications, irregularities, or other devices may damage the SOFIA™ Distal Access Catheter and potentially affect its insertion or removal.

Maintain perfusion of heparinized saline for inner lumen of the SOFIA™ Distal Access Catheter to prevent thrombus formation.

The hydrophilic coating on the SOFIA™ Distal Access Catheter should be hydrated with heparinized saline before use. Keep the coating hydrated and do not allow the coating to dry.

**POTENTIAL COMPLICATIONS**

Potential complications include, but are not limited to: vessel or aneurysm perforation, vasospasm, hematoma at the site of entry, embolism, ischemia, intracerebral/intracranial hemorrhage, pseudo aneurysm, seizure, stroke, infection, vessel dissection, thrombus formation, and death.

**COMPATIBILITY**

Refer to product label for device dimensions. Use the information on labeling provided with other devices to determine device compatibility.

**PREPARATION FOR USE**

1. Carefully remove the SOFIA™ Distal Access Catheter and the Introducer Sheath from the package.



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2. Inspect the SOFIA™ Distal Access Catheter for any damage.
   **WARNING**: Do not use the device if any damages or irregularities are observed.

   If steam shaping is desired, use the technique outlined in the step 3. Otherwise proceed to the step 4.

3. **STEAM SHAPING**
   a. Bend the Shaping Mandrel for desired shape.
      **WARNING**: Do not make more than 90 degree angle on the Shaping Mandrel. Steaming of the distal tip with more than 90 degree angle may result in damage to the device.
   b. Carefully insert the Shaping Mandrel into the distal tip of the SOFIA™ Distal Access Catheter.
   c. Hold the distal segment together with the Shaping Mandrel and steam it for 30 seconds.
   d. Immediately place the shaped distal segment into heparinized saline to set the shape.
   e. Inspect the distal shaft for any damage.
      **WARNING**: Do not use the device if any damages or irregularities are observed.
   f. Remove the Shaping Mandrel from the SOFIA™ Distal Access Catheter.
      Do not use the device if any damages or irregularities are observed.
      **WARNING**: Do not repeat steaming of the same device more than once, which may result in damage to the device.

4. Flush the lumen of the SOFIA™ Distal Access Catheter with heparinized saline. Attach a rotating hemostatic valve (RHV) to the proximal hub of the SOFIA™ Distal Access Catheter. Set up the line for perfusion of heparinized saline through the sidearm of the RHV.

5. Hydrate the hydrophilic coating on the SOFIA™ Distal Access Catheter with heparinized saline before use. Keep the coating hydrated and do not allow the coating to dry.

**DELIVERY OF THE HYBRID DISTAL ACCESS CATHETER**

6. Go to the step 7 or 8, depending on the situation described below and choose appropriate devices for navigation of the SOFIA™ Distal Access Catheter.

7. **Navigation through the vasculature, except for the intracranial vasculature**
   a. Prepare 0.035” or 0.038” Guidewire for navigation of the SOFIA™ Distal Access Catheter.
   b. Insert the guidewire into the SOFIA™ Distal Access Catheter and advance the Guidewire until the Guidewire and the SOFIA™ Distal Access Catheter are aligned at the distal end.
   c. Using the Introducer Sheath provided in the package, carefully insert the SOFIA™ Distal Access Catheter and the Guidewire through a hemostatic valve of the femoral sheath
   d. Remove the Introducer Sheath from the SOFIA™ Distal Access Catheter once the distal shaft of the SOFIA™ Distal Access Catheter is placed inside the patient body.
      **WARNING:** Introducer Sheath is not intended for use inside the patient body.
   e. Under fluoroscopic guidance, advance or withdraw the SOFIA™ Distal Access Catheter over the guidewire until desired position is attained or before the intracranial position is achieved. Select vessels by slowly torqueing the SOFIA™ Distal Access Catheter if necessary.
      **WARNING**: Do not advance or withdraw the device when excessive resistance is met until the cause of resistance is determined.
      **WARNING**: Torqueing the SOFIA™ Distal Access Catheter excessively while kinked may damage the device resulting in separation of the device. Withdraw the entire device (the device, Microcatheter, and Guidewire) if the device is severely kinked.
      **WARNING**: Do not exceed 2070 kPa (300 psi) maximum recommended infusion pressure. Excess pressure may damage the device or injure the patient. Carefully monitor placement of the distal tip when using a power injector to infuse.
   f. Go to the step 8 for navigation through the intracranial vasculatures. Otherwise proceed to the step 9.

8. **Navigation through the intracranial vasculature**
   a. Prepare Microcatheter and compatible Guidewire for navigation of the SOFIA™ Distal Access Catheter.
   b. Slowly remove, if any, devices previously inserted in the SOFIA™ Distal Access Catheter. Insert the Microcatheter with the Guidewire into the SOFIA™ Distal Access Catheter.

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c. Under fluoroscopic guidance, advance or withdraw the SOFIA™ Distal Access Catheter over the Microcatheter and the Guidewire until desired position is attained. Select vessels by slowly torqueing the SOFIA™ Distal Access Catheter if necessary.
**WARNING**: Do not advance or withdraw the device when excessive resistance is met until the cause of resistance is determined.
**WARNING**: Torqueing the SOFIA™ Distal Distal Access Catheter excessively while kinked may damage the device resulting in separation of the device. Withdraw the entire device (the device, Microcatheter, and Guidewire) if the device is severely kinked.
**WARNING**: Do not exceed 2070 kPa (300 psi) maximum recommended infusion pressure. Excess pressure may damage the device or injure the patient. Carefully monitor placement of the distal tip when using a power injector to infuse.

9. Slowly remove the Guidewire or the Microcatheter if necessary. Make sure that continuous perfusion of heparinized saline is maintained through the sidearm of the RHV.
**NOTE:** The Microcatheter used to navigate the SOFIA™ Distal Access Catheter may be kept for the rest of procedure.

The physician has the discretion to modify described manipulations of the SOFIA™ Distal Access Catheter to accommodate the complexity and variation in procedures. Any technique modification must be consistent with previously described instructions, warnings, precautions and patient safety information.

**STORAGE**

Avoid exposure to water, sunlight, extreme temperatures and high humidity during storage. Store the SOFIA™ Distal Access Catheter under controlled room temperature. See the product label for the device shelf life. Do not use the device beyond the labeled shelf life.

**MATERIALS**

The SOFIA™ Distal Access Catheter does not contain latex or PVC materials.

**SYMBOLS**

| | | | |
|---|---|---|---|
| LOT | Lot Number | | Do Not Reuse |
| REF | Catalog Number | | Attention, Consult Accompanying Documents |
| CONT | Contents | | Use by Date |
| STERILE EO | Sterilized Using Ethylene Oxide | | Date of Manufacture |
| CE | CE Mark | | Manufacturer |
| EC REP | Authorized European Representative | | Non-pyrogenic |

**WARRANTY**
MicroVention, Inc. warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling, storage, cleaning and sterilization of the device as well as factors relating to the patient, diagnosis, treatment, surgical procedure and other matters beyond MicroVention's control directly affect the device and the results obtained from its use. MicroVention's obligation under this warranty is limited to the repair or replacement of this device and MicroVention shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this device. MicroVention neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. MicroVention assumes no liability with respect to devices reused, reprocessed or resterilized and makes no warranties, expressed or implied, including, but not limited to, merchantability or fitness for intended use, with respect to such device.
Prices, specifications and model availability are subject to change without notice.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**Manufacturer:**
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1311 Valencia Avenue
Tustin, CA 92780 USA
Tel: (714) 247-8000

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CE 0297

EC REP

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PD110436 Rev. A
2013-2

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MicroVention TERUMO

October 22, 2013

S 131482/S002

FDA CDRH DMC

OCT 23 2013

Received

Samuel Shimp, Ph.D., Biomedical Engineer
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: eCopy Hold Letter K131482/S002 – SOFIA Distal Access Catheter

The enclosed replacement eCopy is being provided in response to the FDA letter dated October 22, 2013.

Please contact me if you have any questions. Thank you.

Naomi Gong

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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K131482/S002

MicroVention TERUMO

October 18, 2013

FDA/CDRH/DCC
OCT 21 2013
RECEIVED

Samuel Shimp, Ph.D., Biomedical Engineer
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Telephone Hold for K131482/S002 – SOFIA Distal Access Catheter

The following information is being provided in response to the FDA letter dated August 9, 2013.

(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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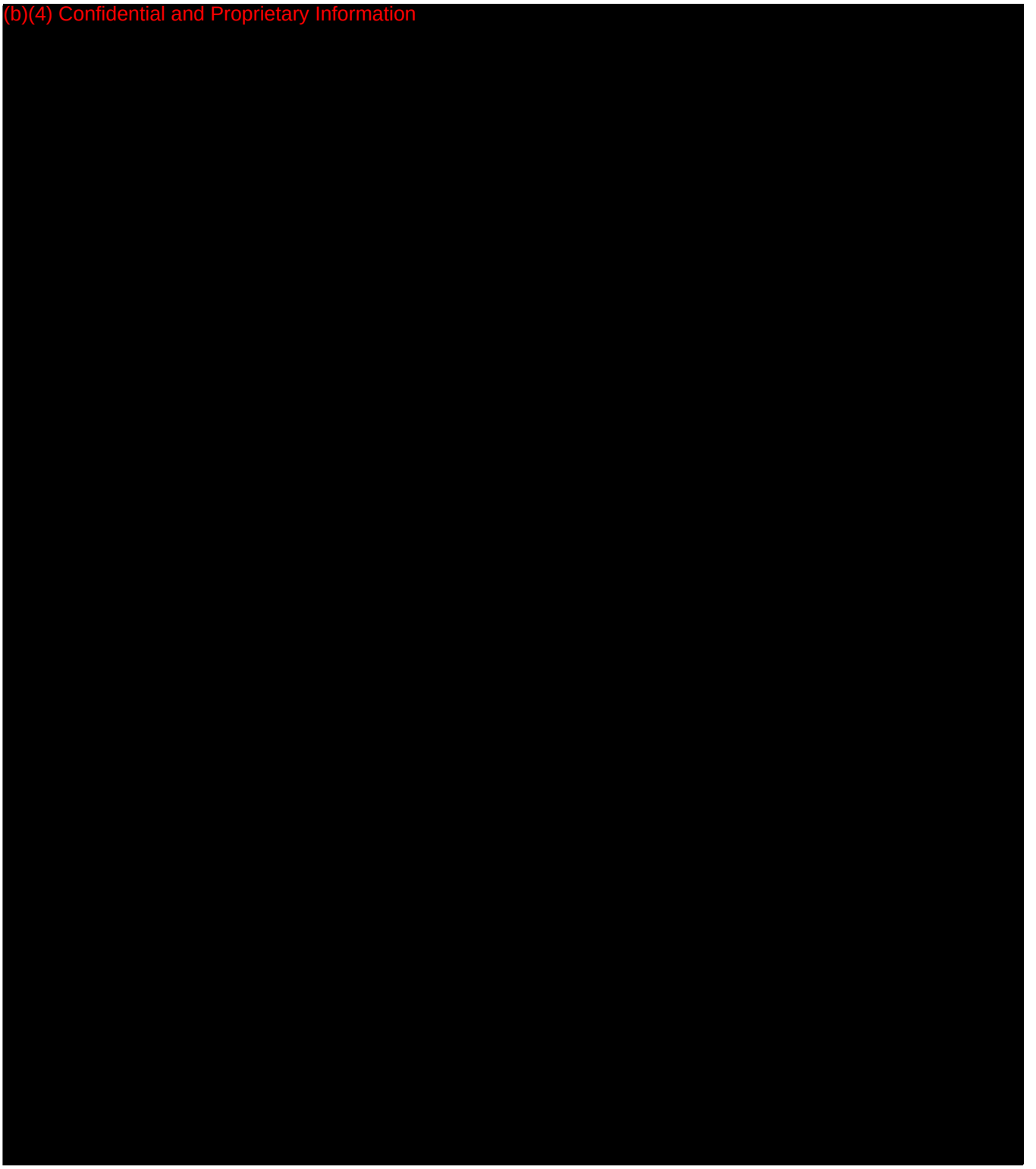



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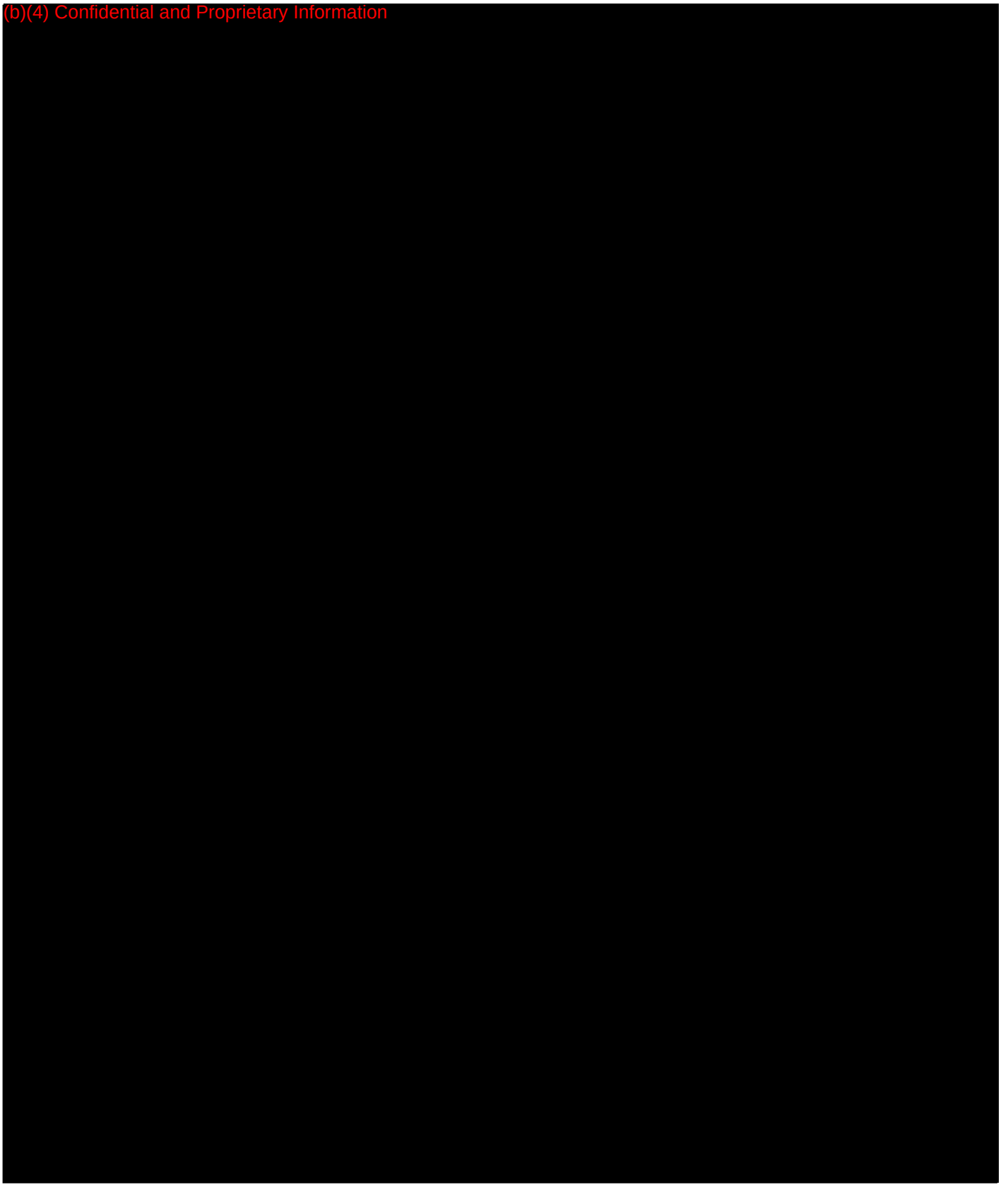



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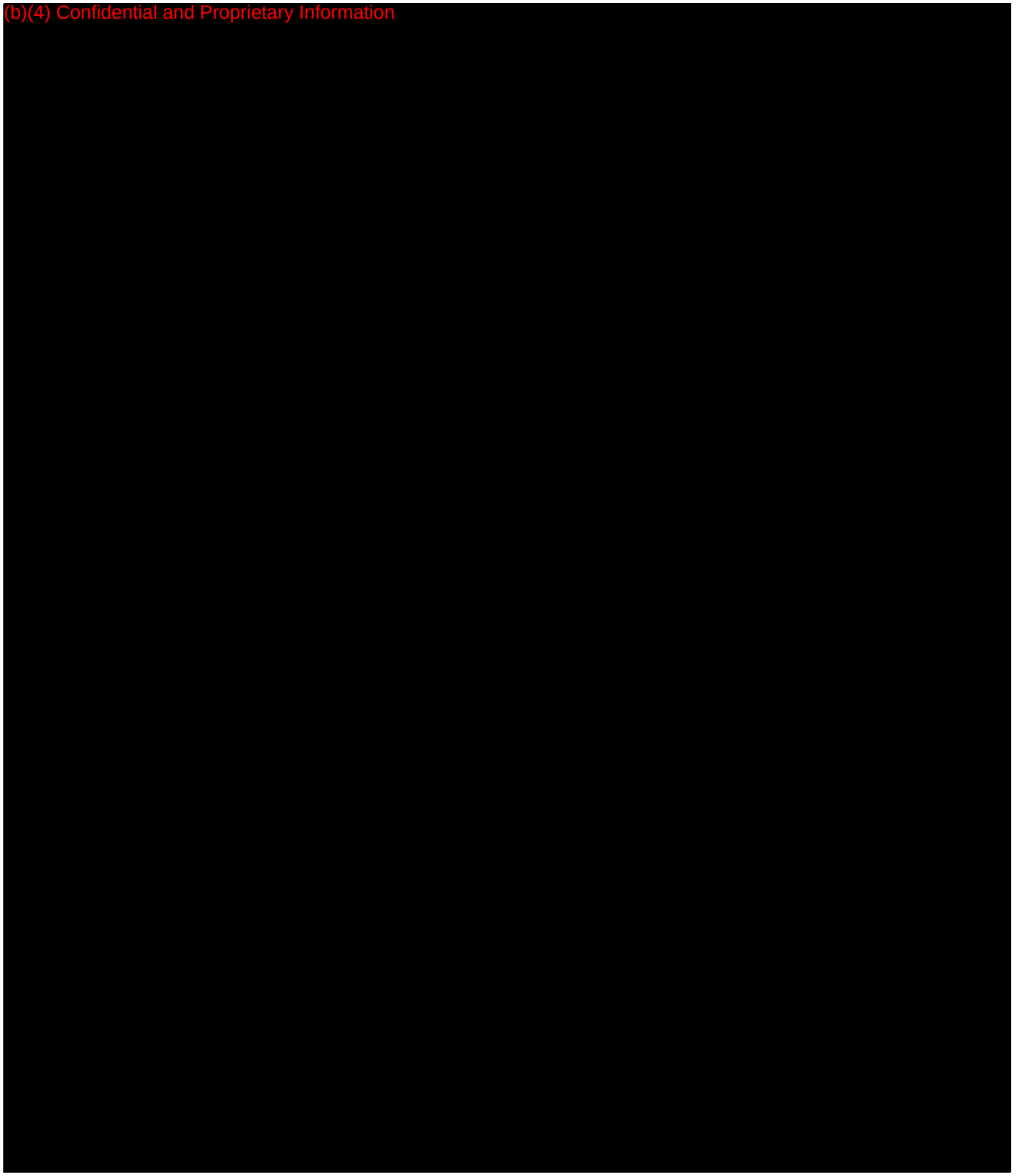



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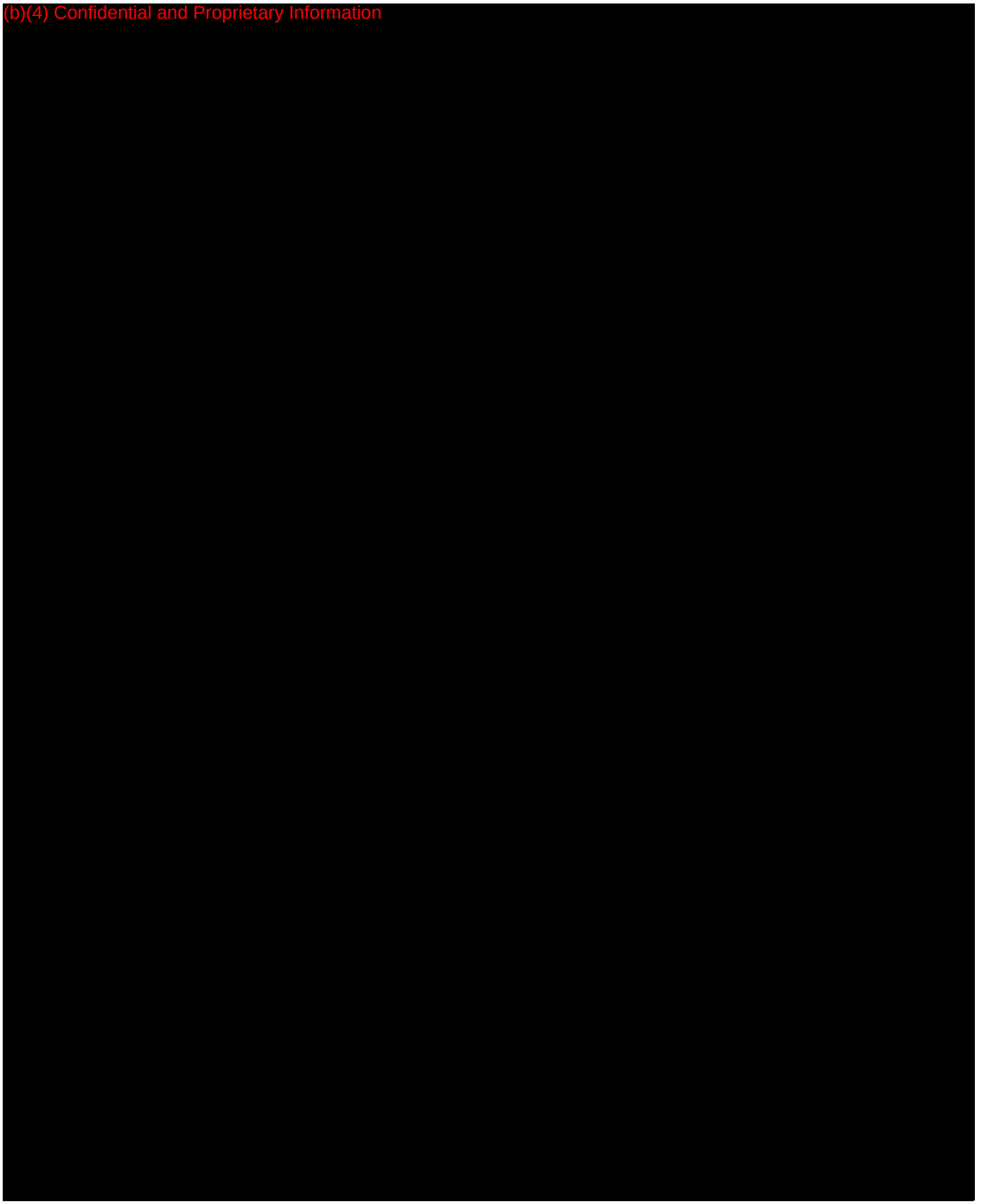



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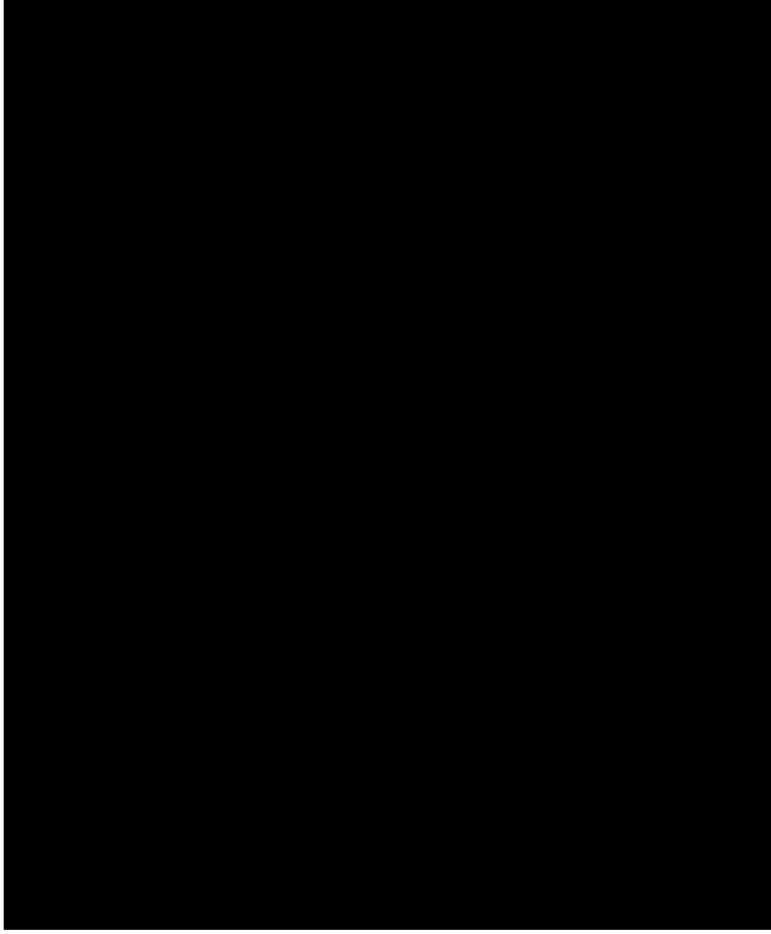



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(b)(4) Confidential and Proprietary Information

[redacted]

A paper copy and an eCopy are being submitted. The eCopy is an exact duplicate of the paper copy. Please contact me if you have any additional questions. Thank you.

Yours truly,

Naomi Gong



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Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

MicroVention TERUMO

October 18, 2013

Samuel Shimp, Ph.D., Biomedical Engineer
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Telephone Hold for K131482/S002 – SOFIA Distal Access Catheter

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(b)(4) Confidential and Proprietary Information

[redacted]

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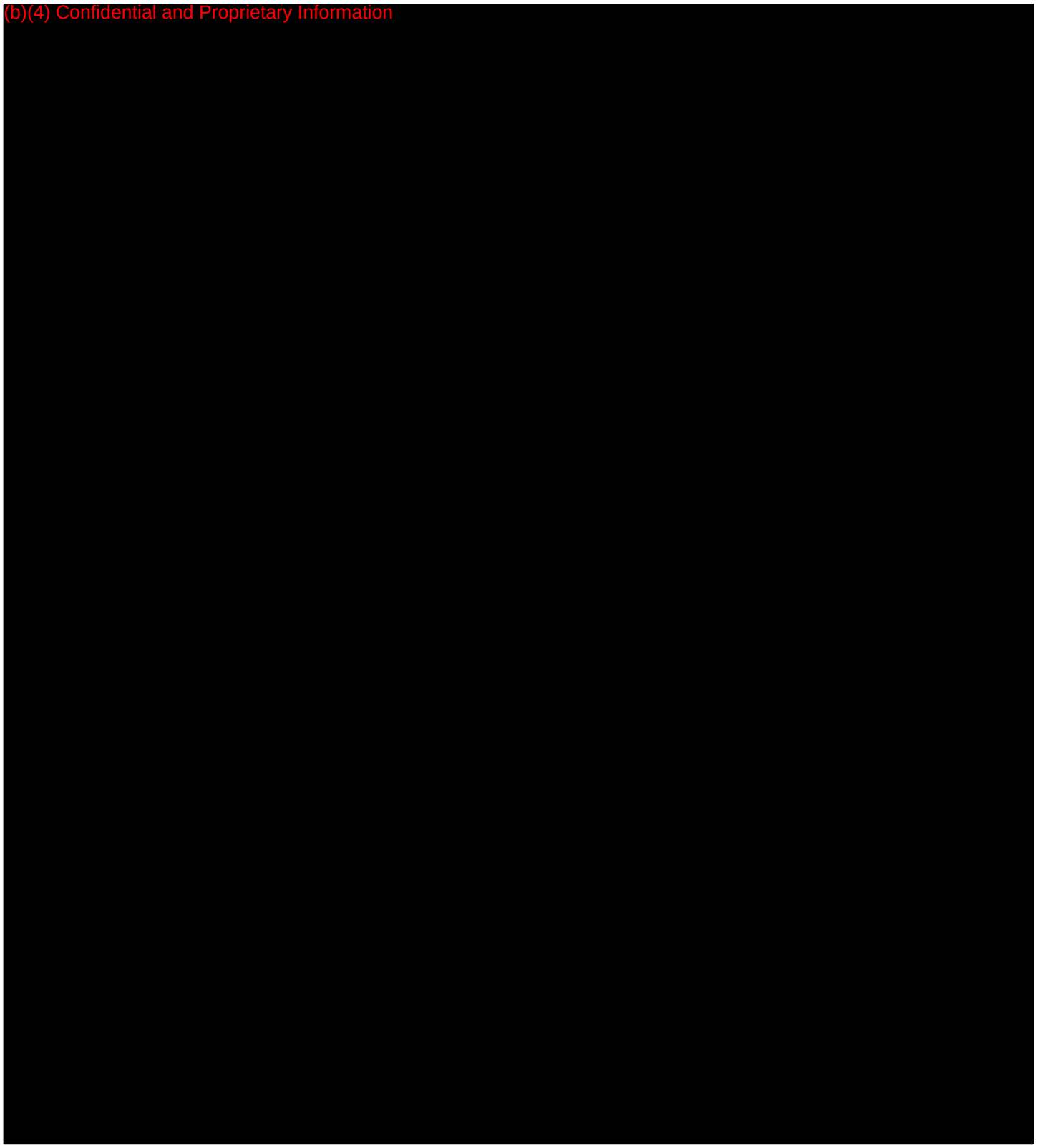


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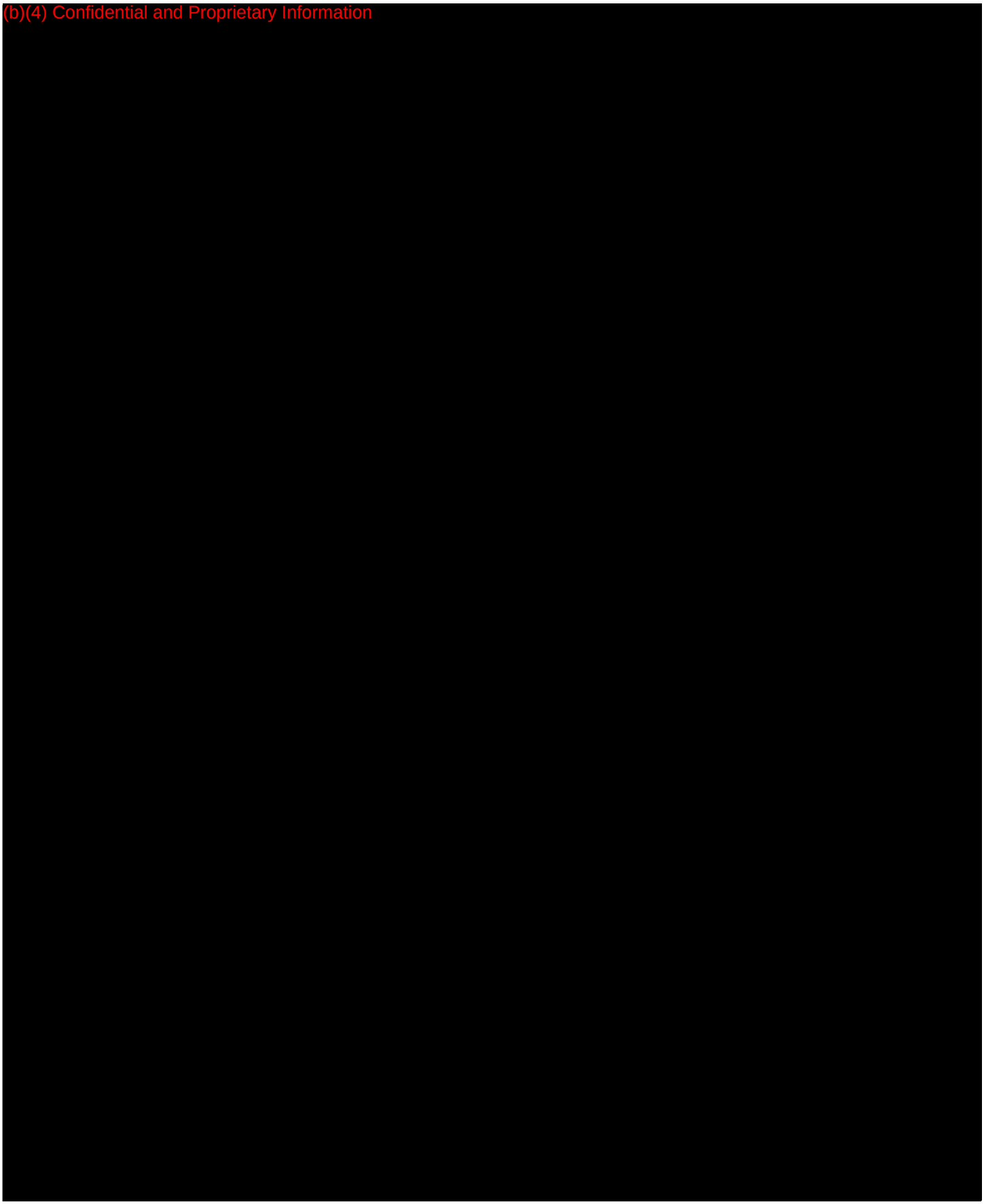

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(b)(4) Confidential and Proprietary Information

[redacted]

A paper copy and an eCopy are being submitted. The eCopy is an exact duplicate of the paper copy. Please contact me if you have any additional questions. Thank you.

Yours truly,

Naomi Gong

Questions? Contact FDA/CDRH/OCE/DID at CDRH-IDESTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
**FOOD AND DRUG ADMINISTRATION**

# CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

| Date of Submission | User Fee Payment ID Number | FDA Submission Document Number *(if known)* |
|---|---|---|
| October 18, 2013 | (b) (4) | K131482 |

## SECTION A TYPE OF SUBMISSION

| PMA | PMA & HDE Supplement | PDP | 510(k) | Request for Feedback |
|---|---|---|---|---|
| ☐ Original Submission | ☐ Regular (180 day) | ☐ Original PDP | ☐ Original Submission: | ☐ Pre-Submission |
| ☐ Premarket Report | ☐ Special | ☐ Notice of Completion | ☐ Traditional | ☐ Informational Meeting |
| ☐ Modular Submission | ☐ Panel Track (PMA Only) | ☐ Amendment to PDP | ☐ Special | ☐ Submision Issue Meeting |
| ☐ Amendment | ☐ 30-day Supplement | | ☐ Abbreviated (Complete section I, Page 5) | ☐ Day 100 Meeting |
| ☐ Report | ☐ 30-day Notice | | ☒ Additional Information | ☐ Agreement Meeting |
| ☐ Report Amendment | ☐ 135-day Supplement | | ☐ Third Party | ☐ Determination Meeting |
| ☐ Licensing Agreement | ☐ Real-time Review | | | ☐ Study Risk Determination |
| | ☐ Amendment to PMA & HDE Supplement | | | ☐ Other *(specify):* |
| | ☐ Other | | | |

| IDE | Humanitarian Device Exemption (HDE) | Class II Exemption Petition | Evaluation of Automatic Class III Designation (De Novo) | Other Submission |
|---|---|---|---|---|
| ☐ Original Submission | ☐ Original Submission | ☐ Original Submission | ☐ Original Submission | ☐ 513(g) |
| ☐ Amendment | ☐ Amendment | ☐ Additional Information | ☐ Additional Information | ☐ Other *(describe submission):* |
| ☐ Supplement | ☐ Supplement | | | |
| | ☐ Report | | | |
| | ☐ Report Amendment | | | |

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

## SECTION B SUBMITTER, APPLICANT OR SPONSOR

| Company / Institution Name | Establishment Registration Number *(if known)* | | |
|---|---|---|---|
| MicroVention, Inc. | 2032493 | | |
| Division Name *(if applicable)* | Phone Number *(including area code)* | | |
| | 714-247-8055 | | |
| Street Address | FAX Number *(including area code)* | | |
| 1311 Valencia Avenue | 714-247-8014 | | |
| City | State / Province | ZIP/Postal Code | Country |
| Tustin | CA | 92780 | U.S. |
| Contact Name | | | |
| Naomi Gong | | | |
| Contact Title | Contact E-mail Address | | |
| Sr. Regulatory Affairs Project Manager | naomi.gong@microvention.com | | |

## SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

| Company / Institution Name | | | |
|---|---|---|---|
| | | | |
| Division Name *(if applicable)* | Phone Number *(including area code)* | | |
| | | | |
| Street Address | FAX Number *(including area code)* | | |
| | | | |
| City | State / Province | ZIP Code | Country |
| | | | |
| Contact Name | | | |
| | | | |
| Contact Title | Contact E-mail Address | | |
| | | | |



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Questions? Contact FDA/CDRH/OCE/DID at CDRH-EDISTATUS@fda.hhs.gov or call 301-796-8118.

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## SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

## SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

## SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☒ Other Reason *(specify)*:

Response to FDA letter dated August 9, 2013



Questions? Contact FDA/CDRH/OCE/DID at CDRH-IDESTATUS@fda.hhs.gov or call 301-796-8118.

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## SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 1 | DQY | 2 | | 3 | | 4 | |
| 5 | | 6 | | 7 | | 8 | |

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

| | *510(k) Number* | | *Trade or Proprietary or Model Name* | | *Manufacturer* |
|---|---|---|---|---|---|
| 1 | K082385 | 1 | Chaperon Guiding Catheter | 1 | MicroVention, Inc.<br>1311 Valencia Avenu, Tustin, CA 92780 |
| 2 | K120917 | 2 | HEADWAY DUO Microcatheter | 2 | MicroVention, Inc.<br>1311 Valencia Avenue, Tustin, CA 92780 |
| 3 | | 3 | | 3 | |
| 4 | | 4 | | 4 | |
| 5 | | 5 | | 5 | |
| 6 | | 6 | | 6 | |

## SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Percutaneous catheter

| | Trade or Proprietary or Model Name for This Device | | Model Number |
|---|---|---|---|
| 1 | SOFIA Distal Access Catheter | 1 | DA5125ST |
| 2 | | 2 | |
| 3 | | 3 | |
| 4 | | 4 | |
| 5 | | 5 | |

FDA document numbers of all prior related submissions *(regardless of outcome)*

| | | | | | |
|---|---|---|---|---|---|
| 1 K131482 | 2 | 3 | 4 | 5 | 6 |
| 7 | 8 | 9 | 10 | 11 | 12 |

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

## SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: DQY

C.F.R. Section *(if applicable)*: 21 CFR 870.1250

Device Class

☐ Class I ☒ Class II
☐ Class III ☐ Unclassified

Classification Panel

Cardiovascular Devices

Indications *(from labeling)*

The SOFIA Distal Access Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries.



Questions? Contact FDA/CDRH/OCE/DID at 301-796-5528 or CDRH-EDISTATUS@fda.hhs.gov or call 301-796-8118.

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| | |
|---|---|
| ***Note:*** Submission of the information entered in Section H does not affect the need to submit device establishment registration. | FDA Document Number *(if known)*<br>K131482 |

## SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

| | | | |
|---|---|---|---|
| ☒ Original ☐ Add ☐ Delete | Facility Establishment Identifier (FEI) Number<br>2032493 | ☒ Manufacturer ☐ Contract Manufacturer | ☐ Contract Sterilizer ☐ Repackager / Relabeler |
| Company / Institution Name<br>MicroVention, Inc. | | Establishment Registration Number<br>2032493 | |
| Division Name *(if applicable)* | | Phone Number *(including area code)*<br>714-247-8000 | |
| Street Address<br>1311 Valencia Avenue | | FAX Number *(including area code)*<br>714-247-8005 | |
| City<br>Tustin | State / Province<br>CA | ZIP Code<br>92780 | Country<br>U.S. |
| Contact Name<br>Naomi Gong | Contact Title<br>Sr. Regulatory Affairs Project Manager | Contact E-mail Address<br>naomi.gong@microvention.com | |

| | | | |
|---|---|---|---|
| ☒ Original ☐ Add ☐ Delete | Facility Establishment Identifier (FEI) Number | ☐ Manufacturer ☐ Contract Manufacturer | ☒ Contract Sterilizer ☐ Repackager / Relabeler |
| Company / Institution Name<br>Sterigenics | | Establishment Registration Number<br>2011171 | |
| Division Name *(if applicable)* | | Phone Number *(including area code)*<br>951-340-0700 | |
| Street Address<br>4900 South Griffith Avenue | | FAX Number *(including area code)* | |
| City<br>Los Angeles | State / Province<br>CA | ZIP Code<br>90058 | Country<br>U.S. |
| Contact Name<br>Sharon Huges | Contact Title<br>Representative | Contact E-mail Address<br>losangelessales@sterigenics.com | |

| | | | |
|---|---|---|---|
| ☐ Original ☐ Add ☐ Delete | Facility Establishment Identifier (FEI) Number | ☐ Manufacturer ☐ Contract Manufacturer | ☐ Contract Sterilizer ☐ Repackager / Relabeler |
| Company / Institution Name | | Establishment Registration Number | |
| Division Name *(if applicable)* | | Phone Number *(including area code)* | |
| Street Address | | FAX Number *(including area code)* | |
| City | State / Province | ZIP Code | Country |
| Contact Name | Contact Title | Contact E-mail Address | |



Questions? Contact FDA/CDRH/OCE/DID at 1-800-CDRH-INFO or CDRHSTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016

## SECTION I UTILIZATION OF STANDARDS

**Note:** Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

| | Standards No. | Standards Organization | Standards Title | Version | Date |
|---|---|---|---|---|---|
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | | | |
| 4 | | | | | |
| 5 | | | | | |
| 6 | | | | | |
| 7 | | | | | |

**Please include any additional standards to be cited on a separate page.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.*



Questions? Contact FDA/CDRH/OCE/DID at 1-800-CDRH-INFO or STATUS@fda.hhs.gov or call 301-796-8118.

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# Attachment 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-1800STATUS@fda.hhs.gov or call 301-796-8118.

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| Bench Testing | Acceptance Criteria | Result |
|---|---|---|
| | • Free from surface defect/no sharp edges<br>• Embedded particulate acceptable if OD is in specification<br>• Distal tip smooth and round at lumen opening<br>• PTFE liner is not delaminated at distal tip | |
| Force at break (distal and hub) | ≥ 2.25 lbf for outer diameters ≥ 0.045" and < 0.072" | Passed |
| Flow rate | Equivalent to or better flow rates than competitor products (for reference only) | N/A |
| Static burst | Catheter shaft will not burst below 46 psi. | Passed |
| Leakage at 46 psi | No liquid leaking from hub and catheter shaft at 46 psi for 30 second duration. | Passed |
| Air leakage | No air leaking into syringe for 15 seconds (ignore air bubbles for the first 5 seconds of the test. | Passed |
| Dynamic burst | • Equivalent or greater burst pressure than competitor product<br>• Microcatheter will not burst below 300 psi | Passed |
| Catheter particle testing | Less than 25 particles greater than 10 microns and less than 3 particles greater than 25 micron | Passed |

As summarized in the table, SOFIA Testing Summary, the following tests were conducted to establish the performance characteristics of the device:

### 14.1. Simulated Use

To verify that SOFIA Catheter meets the established performance specifications in a clinically simulated environment, MicroVention has tested total of 22 samples of SOFIA. Samples underwent simulated use testing that included delivery, trackability (with and without guidewire), guidewire lock-up and catheter ovalization. All samples met the established acceptance criterion of ≥ 3 rating.

The test simulates a neurointerventional embolization procedure using 37°C fluid with catheters, guidewires, and vessel tortuosity.



Questions? Contact FDA/CDRH/OCE/DID at 1-800-638-2041 or CDRH-IDESTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

# Attachment 2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-1800STATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information - Testing

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# Attachment 3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-IDESTATUS@fda.hhs.gov or call 301-796-8118.

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# Attachment 4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-IDESTATUS@fda.hhs.gov or call 301-796-8118.

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# Attachment 5

Questions? Contact FDA/CDRH/OCE/DID at CDRH-IDESTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information - Testing

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# Attachment 8

Questions? Contact FDA/CDRH/OCE/DID at CDRHIDESTATUS@fda.hhs.gov or call 301-796-8118.

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# Attachment 9

Questions? Contact FDA/CDRH/OCE/DID at CDRHFOISTATUS@fda.hhs.gov or call 301-796-8118.

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

# STANDARDS DATA REPORT FOR 510(k)s

**(To be filled in by applicant)**

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 594-2 (1998) Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2

| **Please answer the following questions** | Yes | No |
|---|---|---|
| Is this standard recognized by FDA [2]? | ☒ | ☐ |
| FDA Recognition number [3] | #6-129 | |
| Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? | ☐ | ☒ |
| Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table. | ☐ | ☒ |
| Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? | ☒ | ☐ |
| Does this standard include acceptance criteria? If no, include the results of testing in the 510(k). | ☐ | ☒ |
| Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table. | ☐ | ☒ |
| Were there any deviations or adaptations made in the use of the standard? | ☐ | ☒ |
| If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]? | ☐ | ☐ |
| Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table. | ☐ | ☒ |
| Were there any exclusions from the standard? If yes, report these exclusions in the summary report table. | ☐ | ☒ |
| Is there an FDA guidance [6] that is associated with this standard? | ☐ | ☒ |
| If yes, was the guidance document followed in preparation of this 510k? | ☐ | ☐ |

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm



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## EXTENT OF STANDARD CONFORMANCE
## SUMMARY REPORT TABLE

STANDARD TITLE
SO 594-2 (1998) Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2

### CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| All | (as applicable) | ☒ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|---|---|---|
| | | ☐ Yes ☐ No ☐ N/A |

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

### Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.*


Questions? Contact FDA/CDRH/OCE/DID at CDRH-1500STATUS@fda.hhs.gov or call 301-796-8118.

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# Attachment 10

Questions? Contact FDA/CDRH/OCE/DID at CDRHFOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information -Testing

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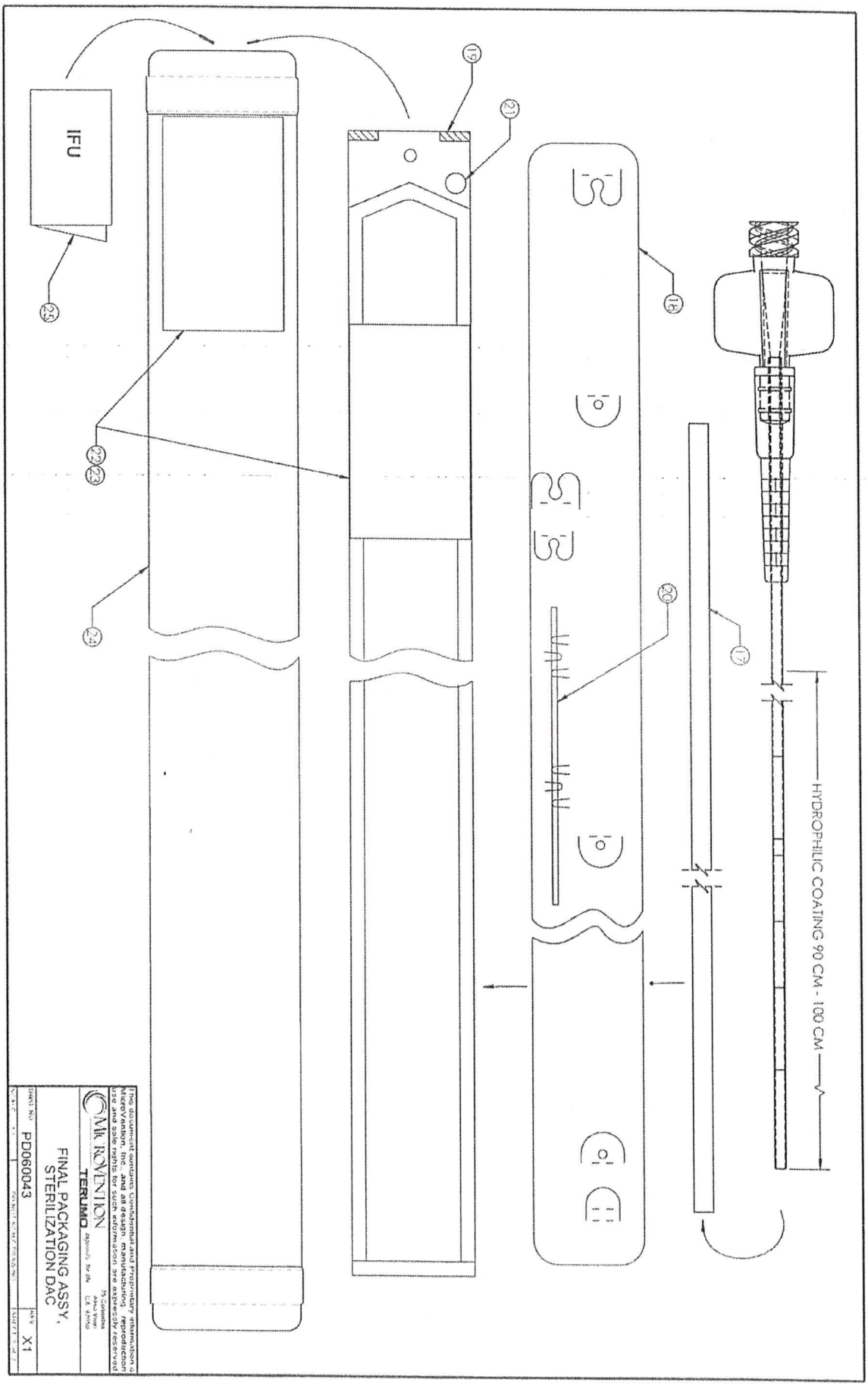
Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

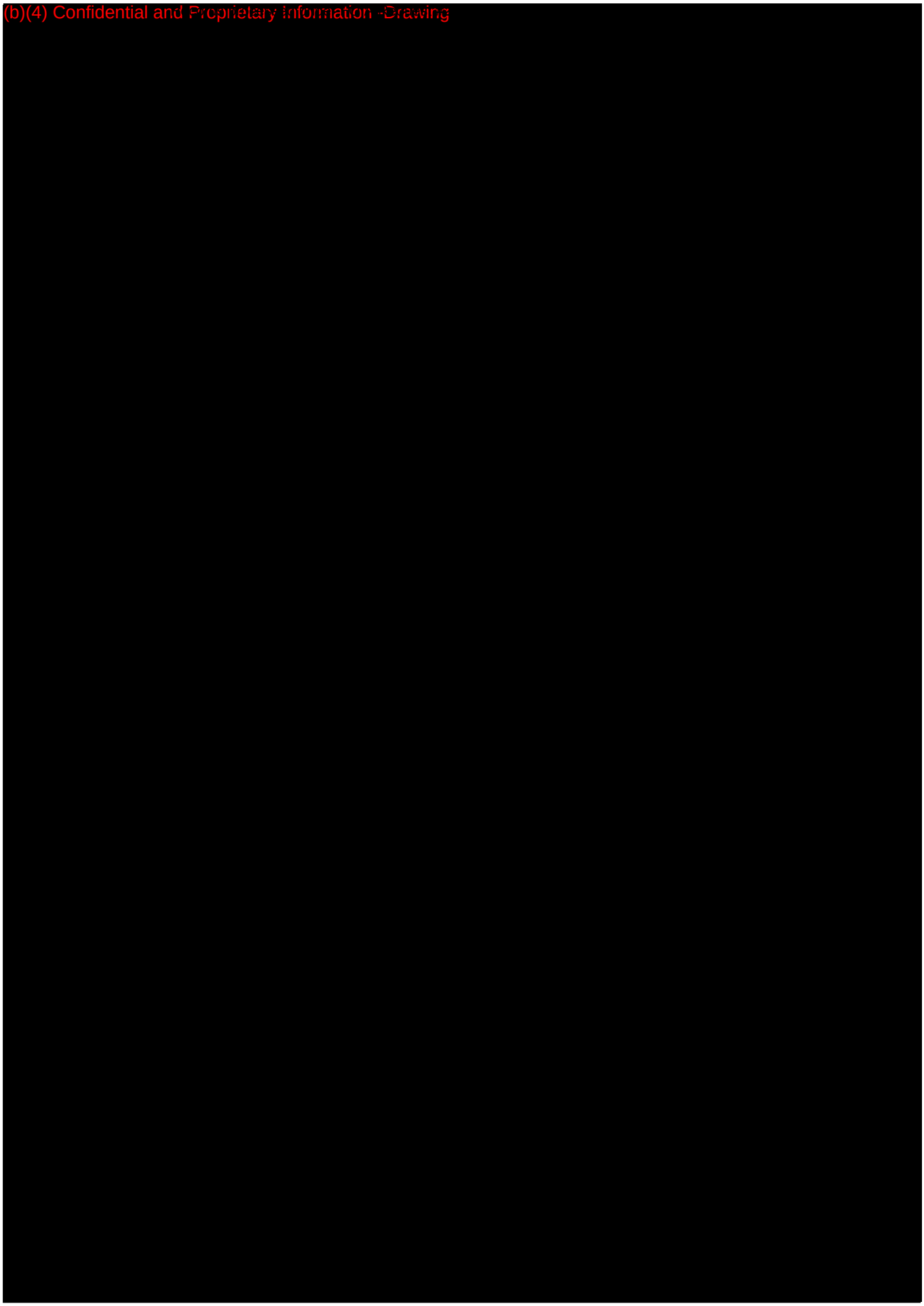
# ATTACHMENT 2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-IDESTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.




Questions? Contact FDA/CDRH/OCE/DID at 1-800-CDRH-INFO or CDRHSTATUS@fda.hhs.gov or call 301-796-8118.


(b)(4) Confidential and Proprietary Information - Drawing

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

# ATTACHMENT 3

Questions? Contact FDA/CDRH/OCE/DID at CDRHIDSTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

# ATTACHMENT 4

Questions? Contact FDA/CDRH/OCE/DID at CDRHDIDSTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information - Study

(b)(4) Confidential and Proprietary Information - Study

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Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

# ATTACHMENT 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information - Testing

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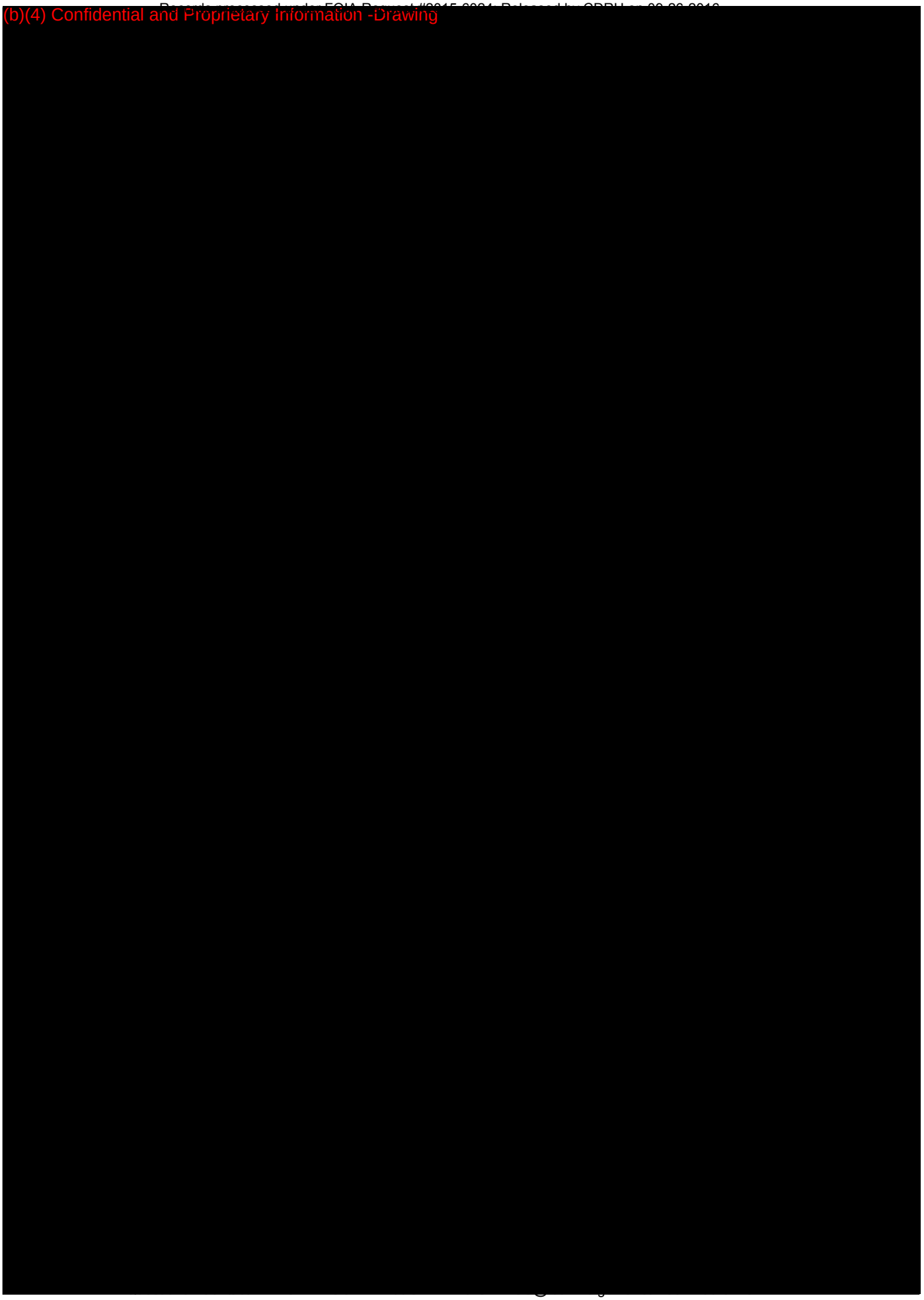
# Attachment 13

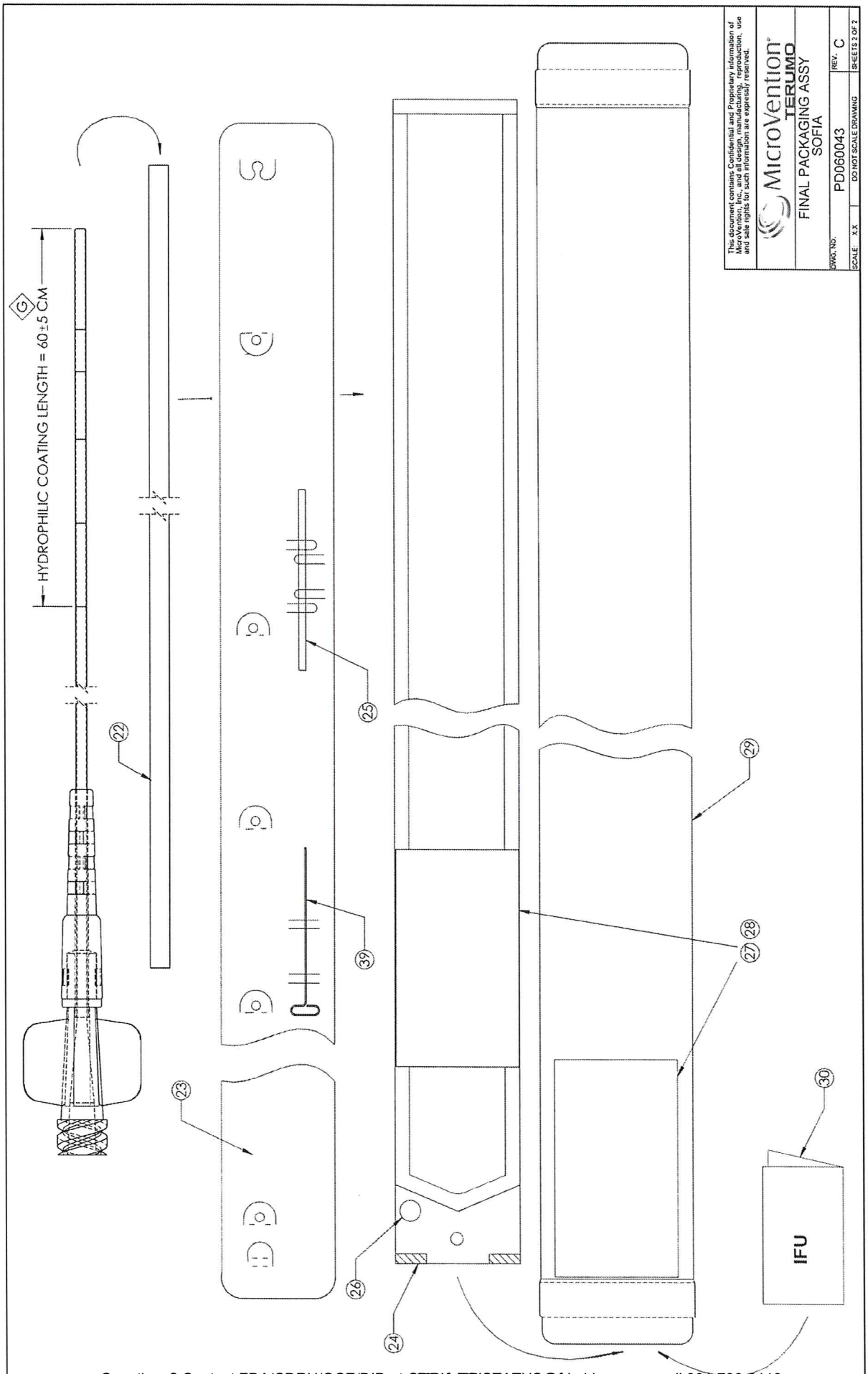
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6004; Released by CDRH on 09-30-2016

(b)(4) Confidential and Proprietary Information -Drawing



Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.




Questions? Contact FDA/CDRH/OCE/DID at CDRH-TRISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information - Testing

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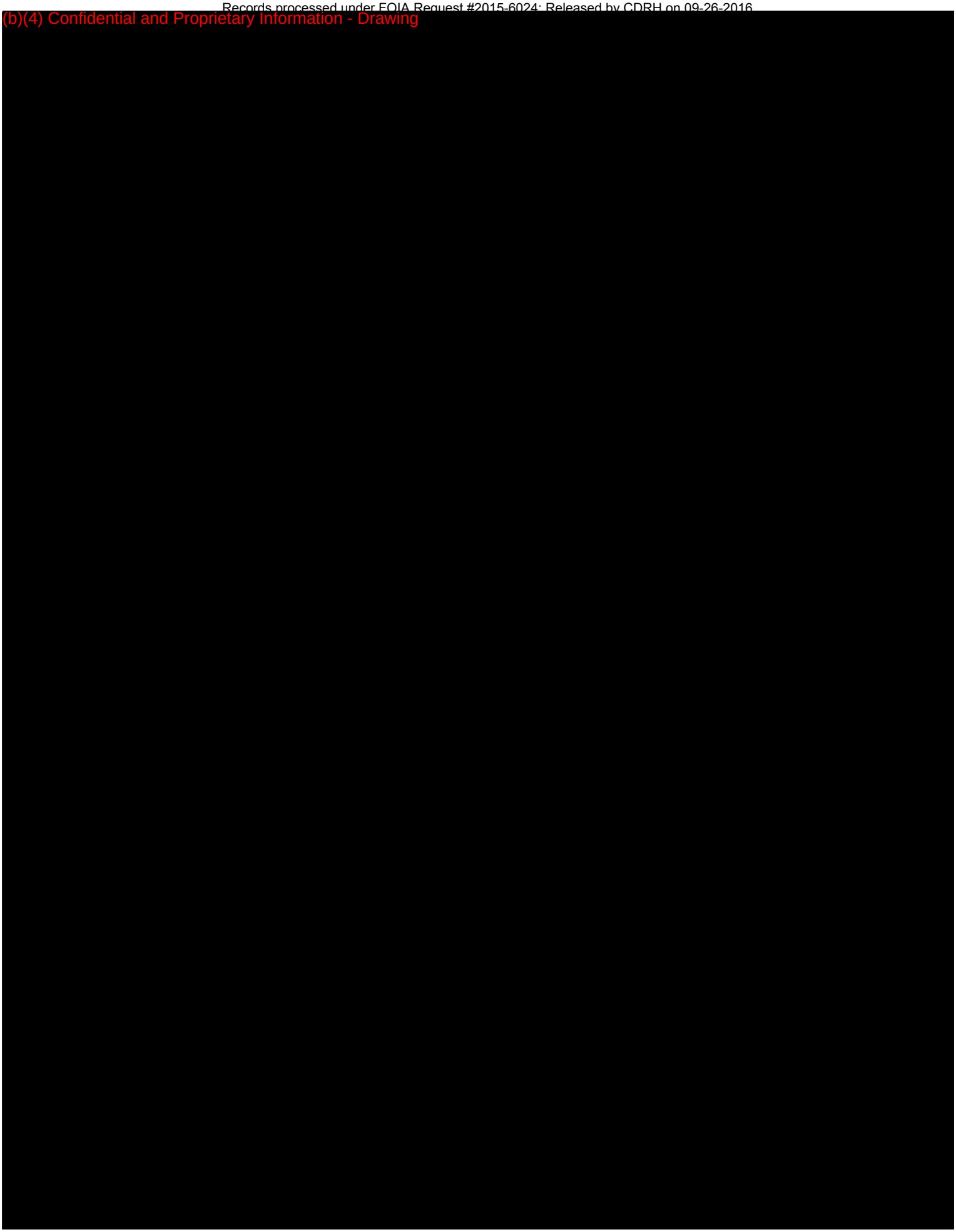
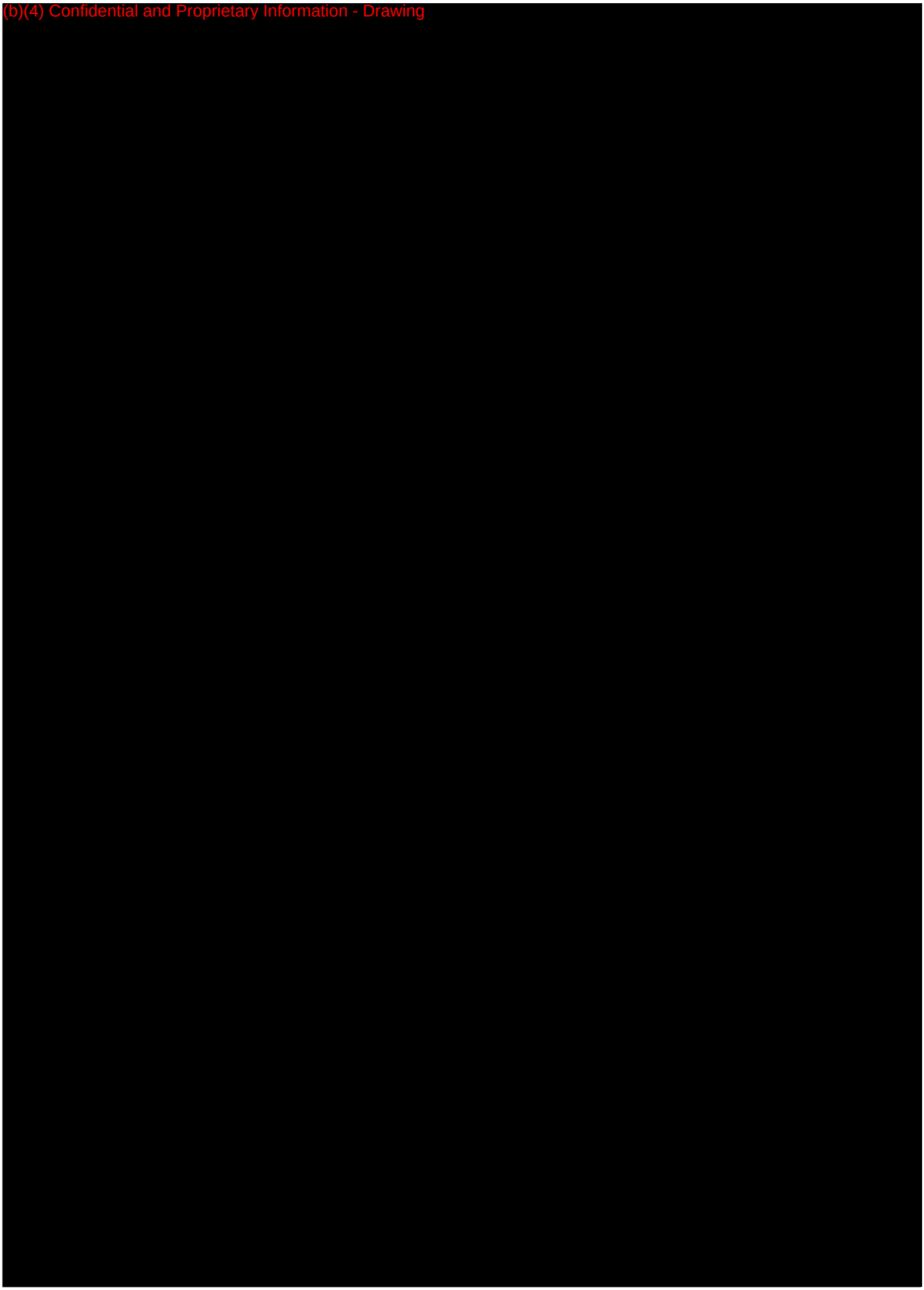
Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

# Attachment 15

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016

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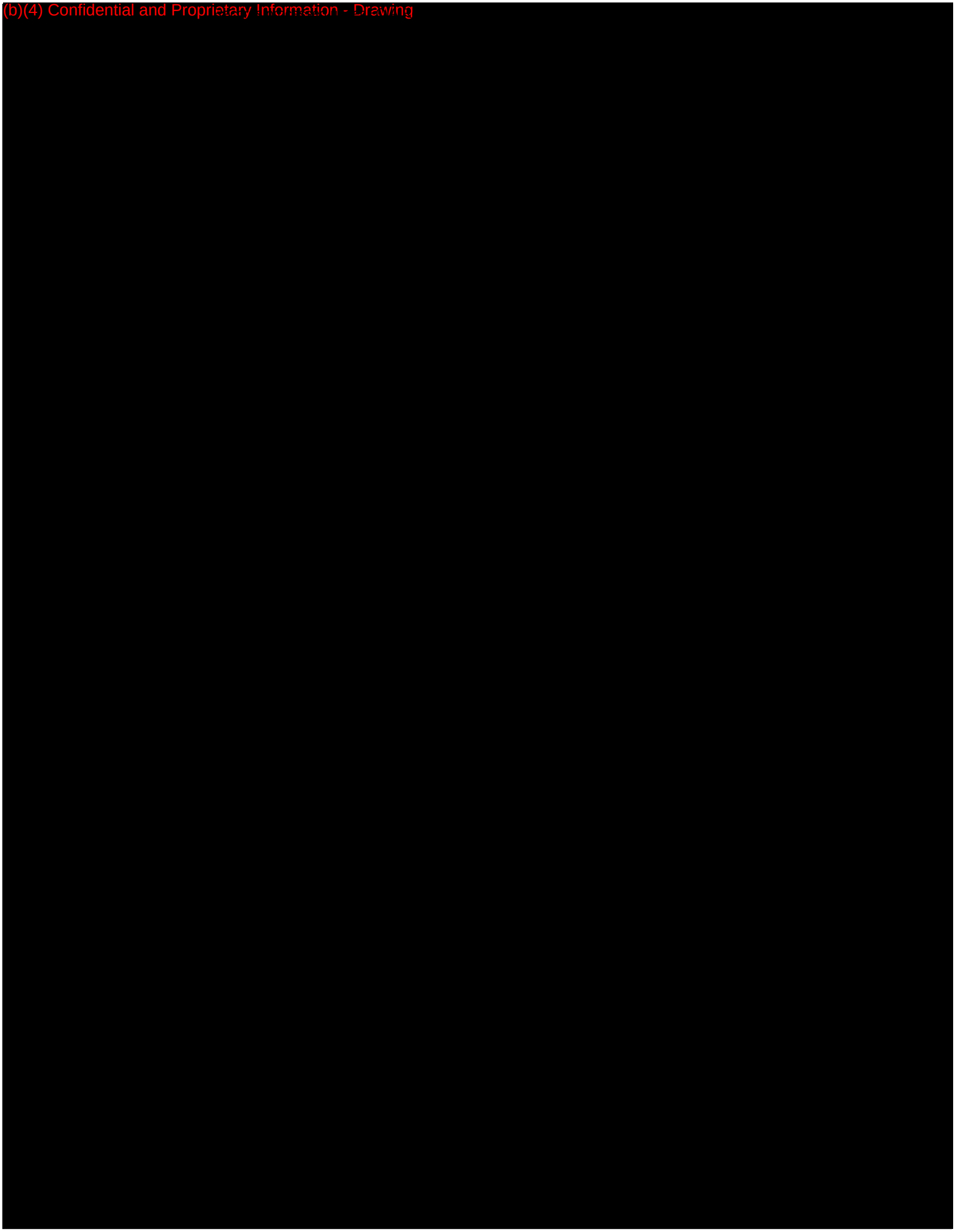
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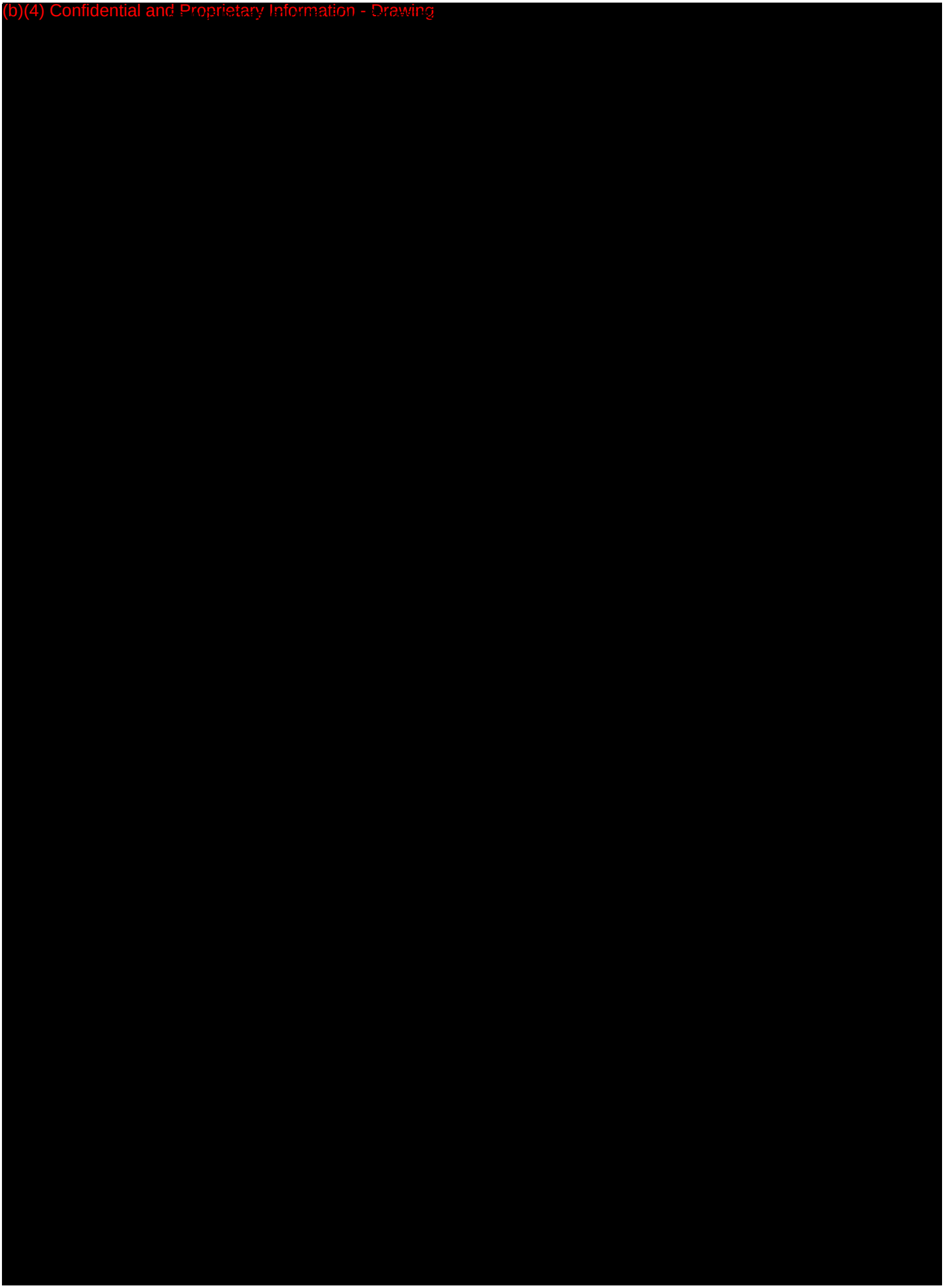
(b)(4) Confidential and Proprietary Information - Drawing

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

# Attachment 16

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

| 510(k) Summary | |
|---|---|
| **Trade Name:** | SOFIA™ Distal Access Catheter |
| **Generic Name:** | Percutaneous Catheter |
| **Classification:** | Class II, 21 CFR 870.1250 (DQY) |
| **Submitted By:** | MicroVention, Inc<br>1311 Valencia Avenue<br>Tustin, California U.S.A. |
| **Contact:** | Naomi Gong |
| **Date:** | 2013 May 21 |
| **Predicate Device:** | Chaperon Guiding Catheter (K082385)<br>HEADWAY DUO Microcatheter (K120917) |

## Device Description:

The SOFIA Distal Access Catheter is a single-lumen, flexible catheter designed with coil and braid reinforcement. The distal segment is steam-shapeable and it has a hydrophilic coating for navigation through the vasculature. The radiopaque marker is located at the distal end of the catheter for visualization under fluoroscopy. An introducer sheath and shaping mandrel are also provided.

## Indications For Use:

The SOFIA Distal Access Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate introduction of diagnostic or therapeutic devices. It is not intended for use in coronary arteries.

Questions? Contact FDA/CDRH/OCE/DID at 301-796-8118 or CDRH-510KSTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

## Technological Comparison:

| | Chaperon Guiding Catheter | SOFIA Distal Access Catheter | HEADWAY DUO Microcatheter |
|---|---|---|---|
| Intended Use | Intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries. | Intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries. | Intended for general intravascular use, including the peripheral and coronary vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as embolization materials. Intended for neurovascular use for the infusion of diagnostic agents, such as contrast media, and therapeutic agents that have been cleared or approved for use in the neurovasculature and are compatible with the inner diameter of the microcatheter. |
| Material | | | |
| Catheter Body | Outer layer of polyester elastomer; stainless steel braid; inner layer of PTFE (polytetrafluoroehthylene). | Outer layer of polyurethane elastomer (Polyblend and Pellethane), polyether block amide (Pebax) and polyamide (Grilamid); inner layer of stainless steel braid/coil, PTFE and polyolefin elastomer | Outer layer of polyether block amide (Pebax) and polyamide (Grilamid); inner layer of stainless steel braid/coil and PTFE |
| Marker | Tungsten | Platinum/Iridium | Platinum/Iridium |
| Hub | Nylon | Nylon | Nylon |
| Strain Relief | Polyester elastomer | Polyurethane | Pebax |
| Introducer | Not applicable | Pebax | Pebax |
| Shaping Mandrel | Not applicable | Stainless steel | Stainless steel |

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

| | Chaperon Guiding Catheter | SOFIA Distal Access Catheter | HEADWAY DUO Microcatheter |
|---|---|---|---|
| Catheter size | 5 F (outer catheter) | 5 F | 1.6 - 2.1 F |
| ID | 0.059 inch (1.5 mm) | 0.055 inch (1.4 mm) | 0.0165 inch (0.42 mm) |
| OD | 0.068 inch (1.7 mm) | 0.068 inch (1.7 mm) | 0.023 – 0.0275 inch (0.58 – 0.70 mm) |
| Effective Length | 95 cm (outer)<br>117 cm (inner) | 125 cm | 157 and 168 cm |
| Coating | Hydrophilic coating (Terumo proprietary coating) | Hydrophilic coating (b) (4) [redacted] | Hydrophilic coating (b) (4) [redacted] |
| Tip Configuration | Preshaped | Steam shapeable by user | Steam shapeable by user |
| Guidewire Compatibility | 0.035 inch or 0.038 inch | 0.035 inch or 0.038 inch | 0.014 inch or smaller |
| Accessories | N/A | Introducer sheath and shaping mandrel | Introducer sheath and shaping mandrel |
| Method of Supply | Sterile and single use | Sterile and single use | Sterile and single use |
| Sterilization Method | Ethylene Oxide | Ethylene Oxide | Ethylene Oxide |
| Packaging Configuration | Catheter placed on packaging card that is inserted into Tyvek® pouch. Pouch and IFU placed in bleached sulfate carton box. | Catheter placed into a HDPE dispenser tube. Dispenser tube, introducer and shaping mandrel placed on a polyethylene packaging card that is inserted into a Tyvek® pouch. Pouch and IFU placed in bleached sulfate carton box. | Catheter placed into a polyethylene dispenser hoop. Introducer and shaping mandrel placed on polyethylene packaging card. Dispenser hoop and packaging card inserted into Tyvek® pouch. Pouch and IFU placed in bleached sulfate carton box. |

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

## Verification and Test Summary:

| **Bench Testing** | | |
|---|---|---|
| **Test** | **Results** | **Conclusions** |
| Simulated Use | Test articles achieved a rating $\geq 3$ for preparation/ease of assembly, introducer sheath interaction, introducer peel away, tracking with guidewire/microcatheter, microcatheter/guidewire lockup, lubricity and durability of hydrophilic coating, microcatheter/ guidewire removal, removal/ aspiration of clot, mechanical clot retriever and stent delivery with no particles | Device performs as intended under simulated use conditions |
| Equipment Interface | Test articles compatible with 0.035-inch and 0.038-inch guidewires, 6F or larger guide catheter/guiding sheath, common RHVs using insertion tool, stopcocks and $\leq$ 0.027-inch microcatheters | Device compatible with recommended accessories commonly used in intravascular procedures |
| Dimensional and Physical Attributes | Test articles met the specified dimensional requirements for catheter OD, catheter ID, overall working length, length of distal section, length of distal tip to marker band and total length of hub/strain relief | Device met established dimensional and physical specifications |
| Kink Resistance | No kinks at 1 cm, 4 cm, 12 cm and 25 cm from distal tip when wrapped around 0.025-inch and 0.030-inch pin gauges<br><br>No kinks noted during simulated use testing | Device resistant to kinking around small radii turns |
| Tip Shapeability | Tip angle of test article equivalent to competitive devices after steam shaping using mandrel with an angle of approximately $90^{o}$ | Shapeability of distal tip after steam shaping equivalent to competitive devices |
| Radio Detectability | Distal marker band visible under fluoroscopy | Device radiopacity equivalent to or better than predicate and competitive devices |

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

| **Bench Testing** | | |
|---|---|---|
| **Test** | **Results** | **Conclusions** |
| Gauging (ISO 594-2) | Gauging pin and hub align in limit planes | Device hub meets the requirements of ISO 594-2 |
| Separation Force (ISO 594-2) | Mating parts separation force greater than 25 N | Device hub meets the requirements of ISO 594-2 |
| Unscrewing Torque (ISO 594-2) | Test article luer remains attached after applying an unscrewing torque not less than 0.02 Nm for a minimum of 10 seconds | Device hub meets the requirements of ISO 594-2 |
| Stress Cracking (ISO 594-2) | No stress cracks on test article hub | Device hub meets the requirements of ISO 594-2 |
| Ease of Assembly (ISO 594-2) | Components fit together securely with no resistance observed between test article luer and reference fitting | Device hub meets the requirements of ISO 594-2 |
| Resistance to Overriding (ISO 594-2) | Test article luer does not override reference fitting threads | Device hub meets the requirements of ISO 594-2 |
| Durability/Lubricity of Hydrophilic Coating | Test article achieved a rating of $\geq 3$ during simulated use testing for coating durability and lubricity. | Device tracks easily with no coating cracking or separation |
| Catheter Stiffness | Device stiffness equivalent to predicate and competitive devices | Device tracks in tortuous anatomy while advancing to target site |
| Torque Strength | No catheter breakage after 50 rotations | Device torque strength same as predicate device |
| Catheter Flexural Fatigue | No flexural fatigue following repeated bending during simulated use testing and repeated hoop stress following pressure and air aspiration testing | Device integrity suitable for intended clinical use |
| Surface Contamination | Test article free from surface contaminants from uncured coating surface particulates > 0.02 $mm^2$, embedded particulates<br><br>Distal tip smooth and tapered<br><br>PTFE inner layer not delaminated | Device integrity suitable for intended clinical use |
| Force at Break (Distal and Hub) | Catheter force at break $\geq$2.25lbf for distal section and hub/catheter junction | Tensile strength test results equivalent to predicate and competitive devices |

Questions? Contact FDA/CDRH/OCE/DID at 301-796-8118 or CDRH-IDESTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

| **Bench Testing** | | |
|---|---|---|
| **Test** | **Results** | **Conclusions** |
| Flow Rate | Flow rate at 100 psi and 300 psi with diagnostic agents (e.g., saline, contrast media) equivalent to or better than competitive devices | Device meets specified requirements for delivery of diagnostic agents |
| Static Burst Pressure | No damage of pressurized catheter at 46 psi | Device integrity suitable for intended clinical use and met requirements of ISO 10555-1 |
| Fluid Leakage at > 46 psi | No liquid leakage from hub and catheter shaft at 46 psi for 30 seconds | Device integrity suitable for intended clinical use and met requirements of ISO 10555-1 |
| Air Leakage | No air leakage at hub into syringe for 15 seconds | Device integrity suitable for intended clinical use and met requirements of ISO 10555-1 |
| Dynamic Burst | Test articles did not burst at or below 300 psi | Device met labeled maximum infusion pressure of 300 psi |
| Particulate Test | Less than 25 particles greater than 10 microns per ml volume and less than 3 particles less than 25 microns per ml volume<br><br>No particles greater than 70 microns | Device met specifications for maximum allowable particles |

| **Biocompatibility** | | |
|---|---|---|
| **Test** | **Results** | **Conclusions** |
| Cytotoxicity – MEM Elution Assay (ISO 10993-5) | Cell culture treated with test article exhibited slight reactivity (Grade 1) | Non-cytotoxic |
| Sensitization/Irritation – Kligman Maximization Test (ISO 10993-10) | Extracts of the test article elicited no reaction at the challenge (0% sensitization) following the induction phase (Grade 1). | Weak allergic potential or sensitizing capacity |
| Sensitization/Irritation – Intracutaneous Injection Test (ISO 10993-10) | Extracts of the test article did not show a significantly greater biological reaction than the sites injected with the control article | Non-irritant |
| Hemocompatibility – Rabbit Blood Direct and Indirect Contact (ISO 10993-4) | The hemolysis index was 0.13% (direct contact) and 0.0% (indirect contact) | Non-hemolytic |

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

| **Biocompatibility** | | |
|---|---|---|
| **Test** | **Results** | **Conclusions** |
| Hemocompatibility – Unactivated Partial Thromboplastin Time Assay Direct Contact (ISO 10993-4) | No statistically significant difference found between the Unactivated Partial Thromboplastin Time (UPTT) of the plasma exposed to the test article and that of the plasma exposed to either the negative control or the untreated control | No effect on coagulation |
| Hemocompatibility – Complement Activation Assay (ISO 10993-4) | C3a and SC5b-9 levels $\leq$ negative and untreated controls | No effect on complement activation |
| Hemocompatibility – Thrombogenicity Study in Dogs (ISO 10993-4) | Minimal thrombosis observed with a Grade 0 in two out of two test sites and two out of two control sites | No significant thrombosis |
| Systemic Toxicity – Systemic Injection Test (ISO 10993-11) | Extracts of test article did not induce a significantly greater biological reaction than the control extracts when injected in Swiss Albino mice | No toxic effects |
| Systemic Toxicity - Rabbit Pyrogen Test (ISO 10993-11) | The temperature increases (maximum) was 0.03°C from baseline | Non-pyrogenic |

## Summary of Substantial Equivalence:

The data presented in this submission demonstrates the technological similarity and equivalency of the SOFIA Distal Access Catheter when compared with the predicate Chaperon Guiding Catheter (K082385) and the HEADWAY DUO Microcatheter (K120917) devices. The devices:

- Have an equivalent intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Are packaged and sterilized using the same methods.

In summary, the SOFIA Distal Access Catheter described in this submission is substantially equivalent to the predicate devices.

Questions? Contact FDA/CDRH/OCE/DID at 888-CDRH-FDA STATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

# Attachment 17

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.


## 6. Predicate Device Information

K082385, MicroVention, Inc., Chaperon Guiding Catheter

K120917, MicroVention, Inc., HEADWAY DUO Microcatheter

## 7. Labeling and Intended Use

Draft labels and Instructions For Use are provided in Appendix 1.

**Intended Use**

The intended use is the same as the predicate device, Chaperon Guiding Catheter and is stated in the product labeling as follows:

*The SOFIA™ Distal Access Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries.*

## 8. Device Overview

The SOFIA Catheter is a single lumen (0.055" or 1.4 mm inner diameter) catheter with a shapeable distal tip. The semi-rigid proximal section transitions to a flexible distal tip to facilitate advancement through the vasculature.

A single radiopaque marker (Pt/Ir) at the distal end facilitates fluoroscopic visualization. The outer surface of the catheter (distal 60 cm) is coated with a hydrophilic polymer coating to reduce friction during navigation in the vasculature.

A luer fitting on the microcatheter hub is used for the attachment of accessories. The hub/strain relief provides kink resistance for the proximal end. The tip configuration is provided straight, but is shapeable by the user. A steam shaping mandrel and introducer sheath accessories are packaged with the catheter.

The device is placed in a dispenser tube to keep the device in position during shipping and handling. The dispenser tube is placed on a packaging card and then placed into a tyvek pouch. The pouch is put into a chipboard carton box prior to sterilization. The device is provided sterile, for single use.

## 9. Device Configurations and Dimensions

The SOFIA Distal Access Catheter has an inner lumen of 0.055" and is recommended to be used with guidewires from 0.035" to 0.038".

| Device | Catalogue Number | Working Length | Outer Diameter/ Inner Diameter | Recommended Guidewire |
|---|---|---|---|---|
| SOFIA Distal Access Catheter | DA5125ST | 125 mm | 0.068"/0.055" (1.7/1.4 mm) | 0.035" to 0.038" |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**From:** Hoang, Quynh T.
**To:** 510K Program
**Cc:** Shimp, Samuel
**Subject:** (Due 6/7) K131482 Conversion fr Special to Traditional. Thanks.
**Date:** Wednesday, June 05, 2013 5:20:07 PM

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Dear 510(k) staff:

For your concurrence is the conversion from a Special to a Traditional.

The conversion form is **file #1**, at
https://docs.fda.gov/share/page/site/submissions/documentlibrary#filter=path%7C%2FReviews%2F510%2528k%2529s%2F2013%2F1401%2520-%25201600%2FK131482%2FReviewer%2520Documents%7C&page=1

Once you are done, we'll inform the sponsor of the conversion and log out the RTAA (for a Traditional).

Thanks.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

# Form for Converting a Special 510(k) to a Traditional or Abbreviated 510(k)

Note: Please send this to 510k Staff electronically. You do not need anyone to sign this in person.

**Date:** 6/28/2013

**Reviewer:** Samuel Shimp

**510(k) Number:** K131482

**Device Name:** Sofia Distal Access Catheter

## Reason for Conversion (select one):

☐ **Change in Indications for Use (please list old and new indications below)**

☐ **Change in Technology (select one):**

☐ **We have not seen this change before in this device type**

☒ **We have seen this change before in this device type, but we need to see the data (please provide a brief statement below regarding why summary data/risk analysis are insufficient)**

☐ **Other (e.g. submission included unsolicited data or sponsor is modifying a device that is not their own – please specify below)**

(b)(4) Confidential and Proprietary Information

[redacted]



Please include this form in the file

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

| Digital Signature Concurrence Table | |
|---|---|
| Reviewer Sign-Off | Samuel Shimp<br>6/28/2013 |
| Branch Chief Sign-Off | Quynh Hoang, 7/2/13 |
| Division Sign-Off **(please obtain before calling or e-mailing POS)** | |
| POS Sign-Off | |

**Date of Phone Conversation with Sponsor:**
(The reviewer or Branch Chief must contact the sponsor to notify them of the conversion. At this time the reviewer or Branch Chief may request additional information that was not submitted in the special.)



Please include this form in the file

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

# MEMORANDUM

Date: July 25, 2013

From: Jeffrey Toy, Ph.D., Toxicologist

Subject: K131482 MicroVention SOFIA Distal Access Catheter Biocompatibility Review

To: The Record

Through: Samuel Shimp, Ph.D.
Team Leader

---

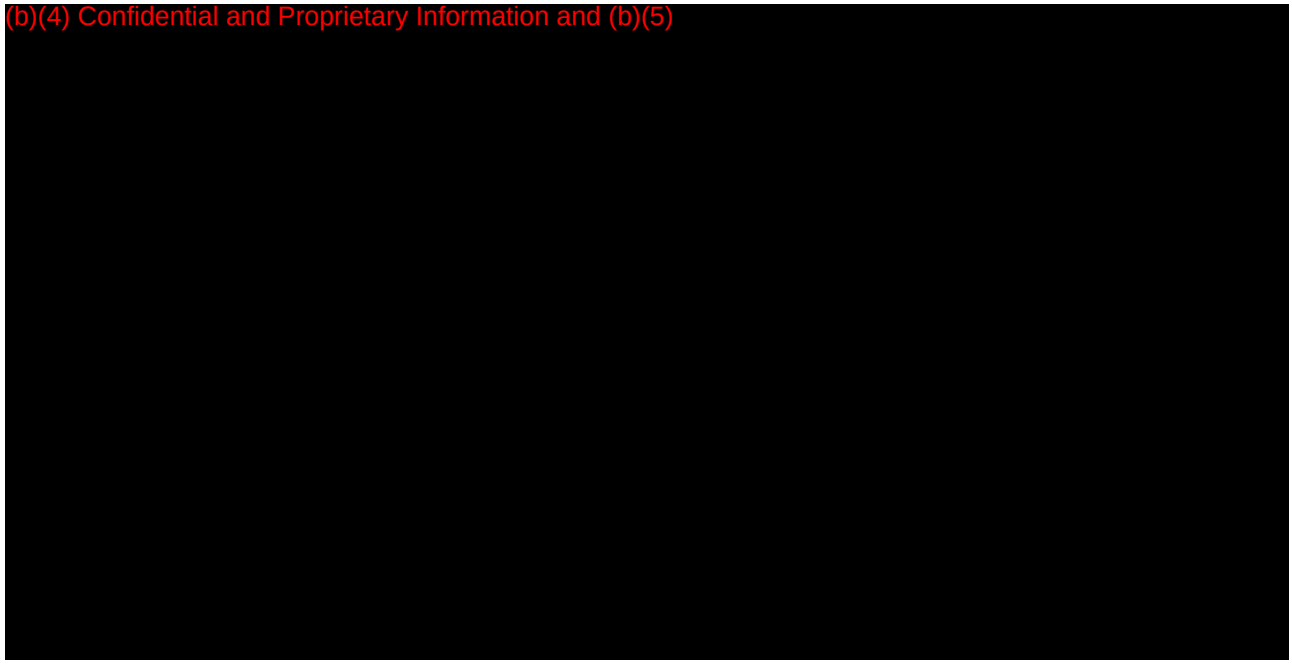
**RECOMMENDATION: ADDITIONAL INFORMATION**

**PURPOSE:**
MIcroVention request 510k clearance for their SOFIA Distal Access Catheter.

*Excerpted text is italicized*

**INDICATION FOR USE**
*The SOFIA Distal Access Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries.*

(b)(4) Confidential and Proprietary Information and (b)(5)

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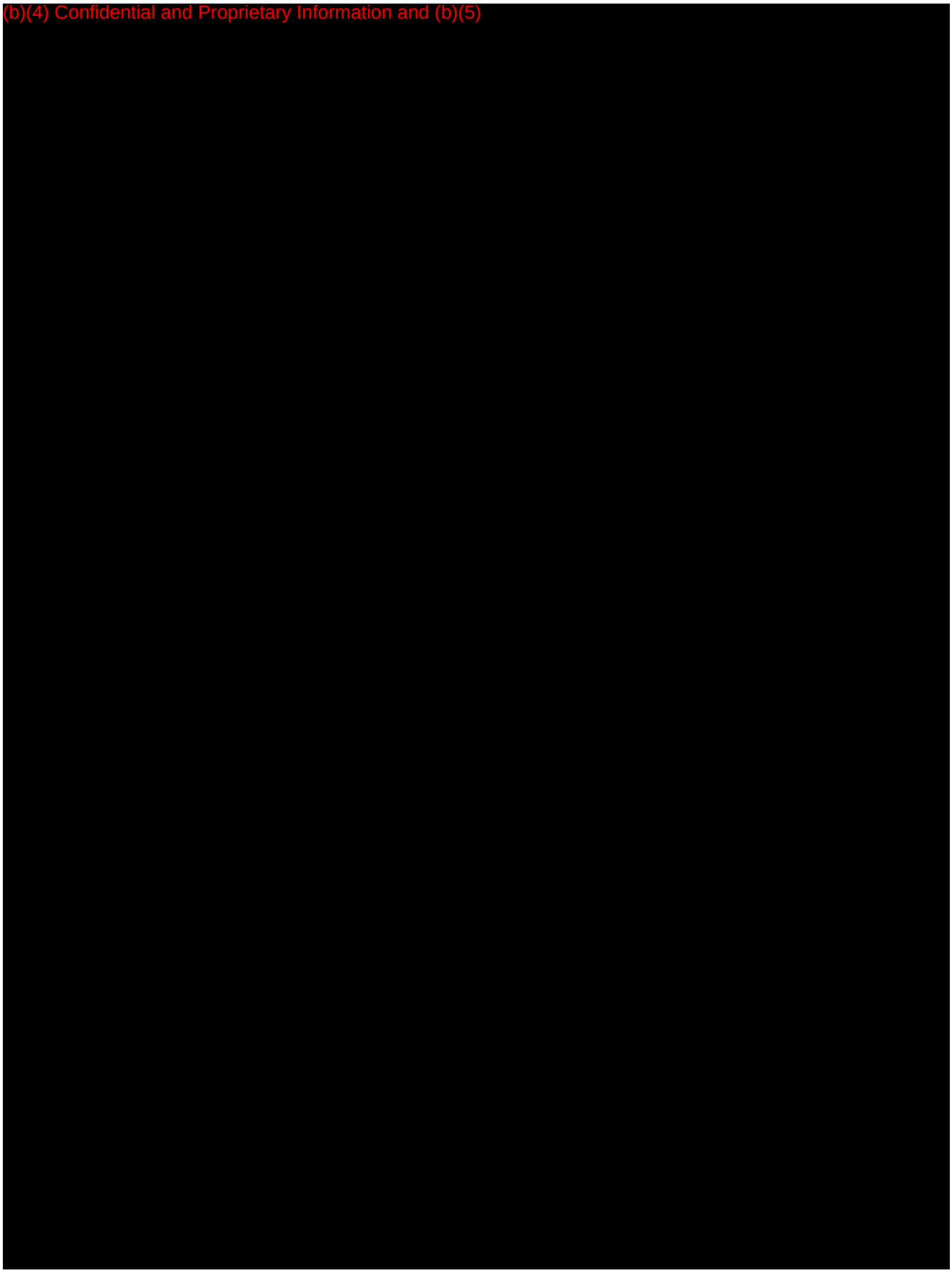


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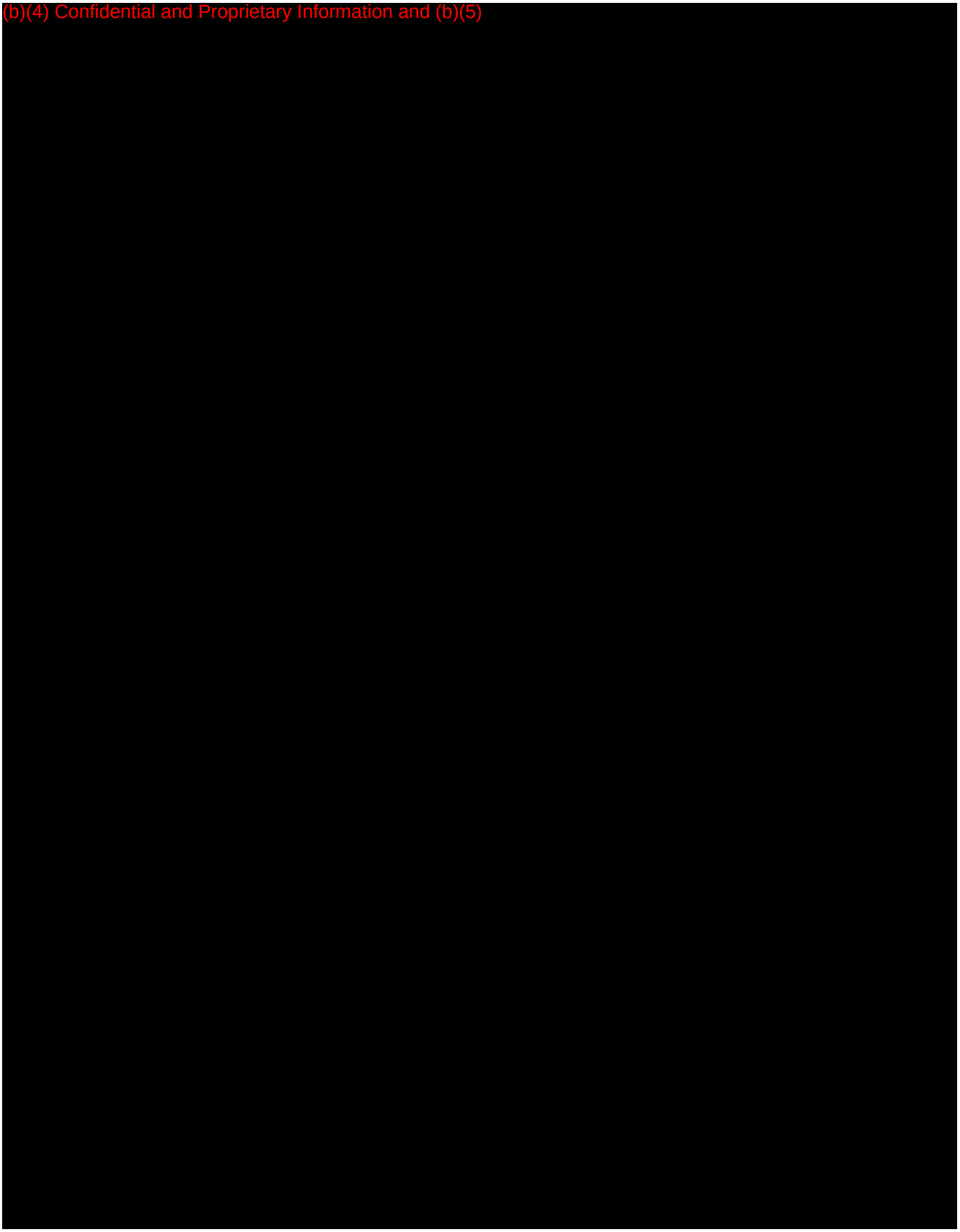


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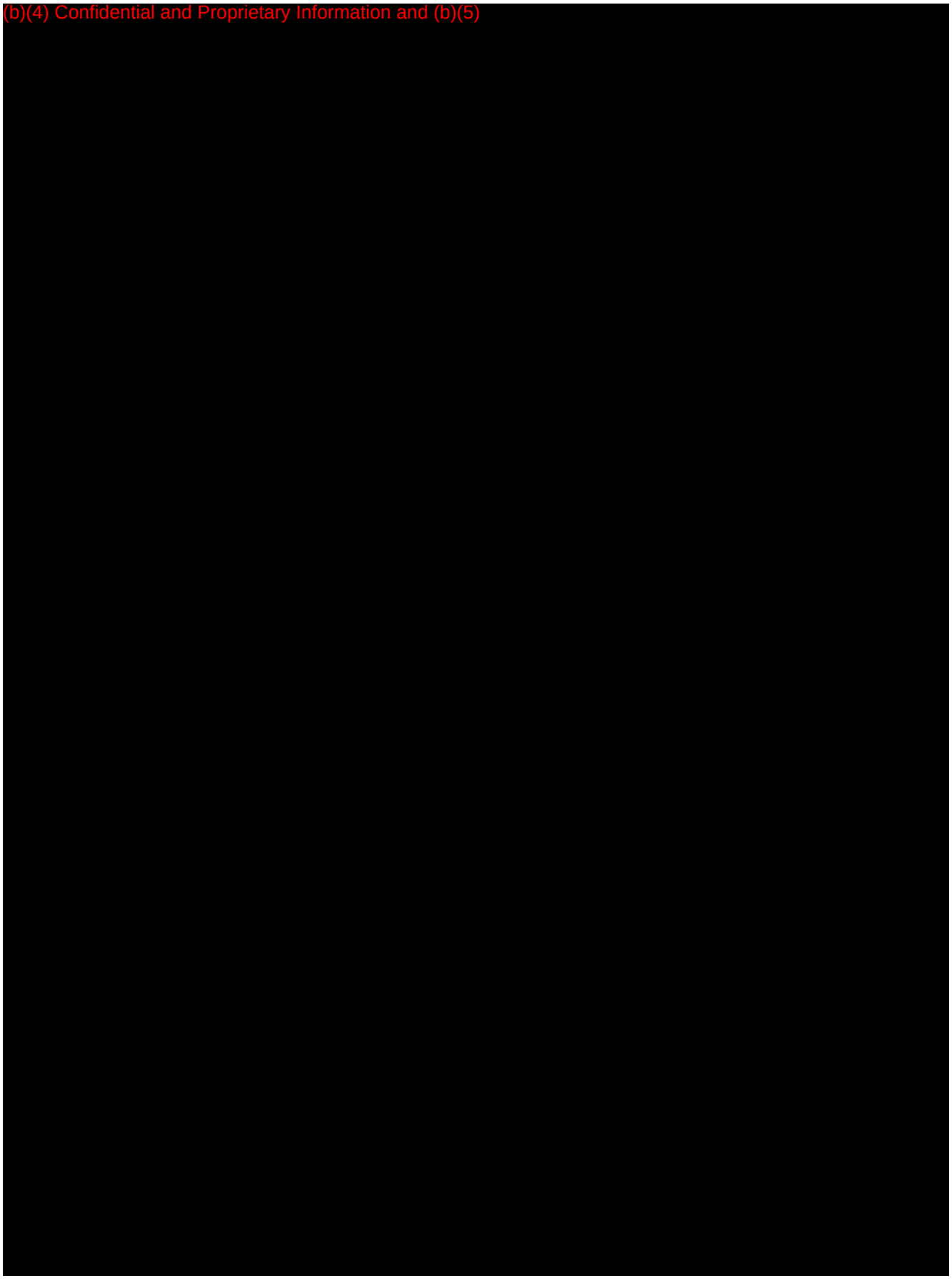


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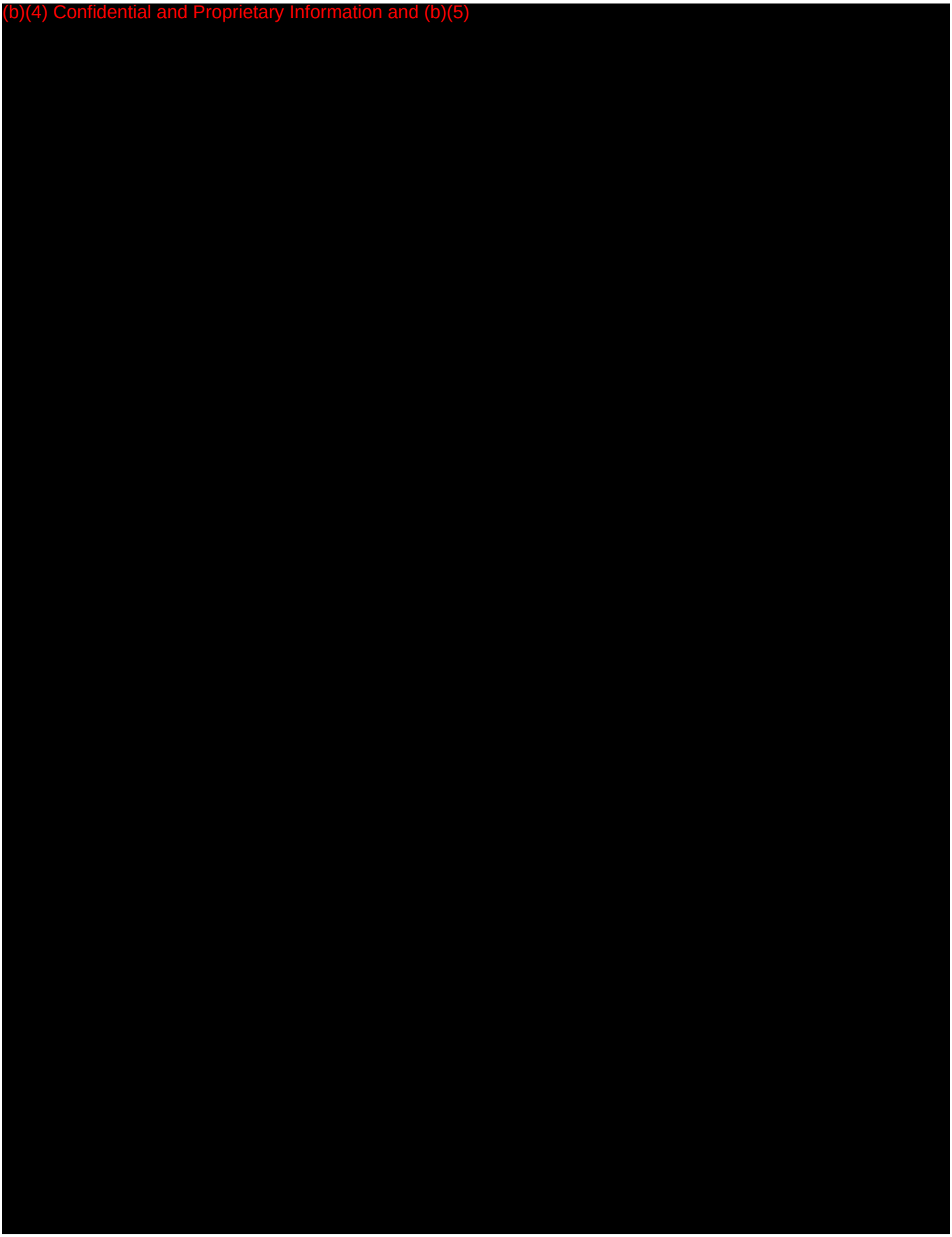


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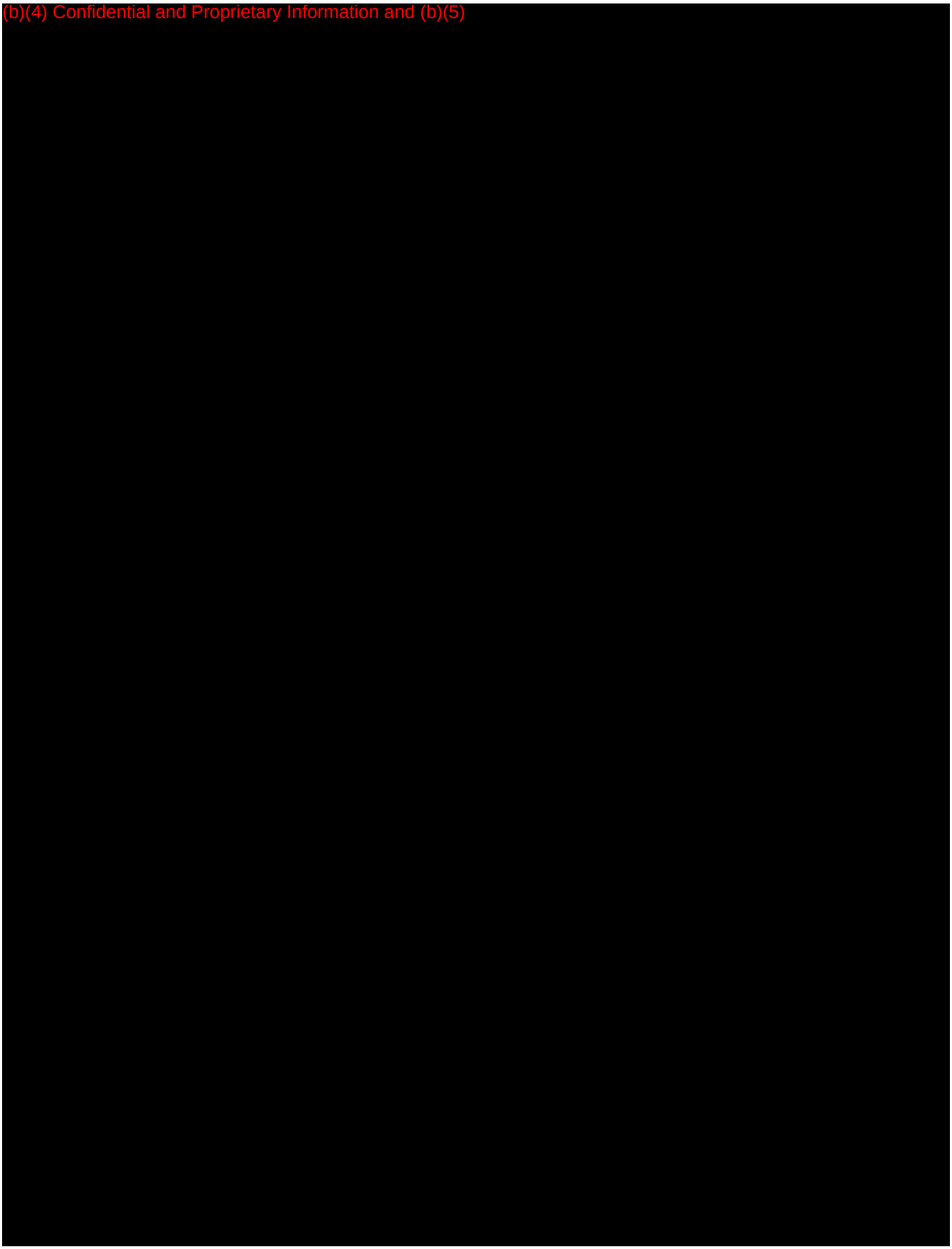


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Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.


(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

## RECOMMENDATION: ADDITIONAL INFORMATION

| | |
|---|---|
| **Reviewer Sign-Off:** | |


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

Date: August 8, 2013

From: Myra Smith, DNPMD/NNDB

To: Samuel Shimp, Ph.D. DNPMD/NNDB

cc: The Record

Subject: K131482/S001 - Microbiology Review
Device Trade Name: SOFIA Distal Access Catheter
Sponsor: MicroVention Inc.

Classification

Generic Name: Percutaneous Catheter Classification:
Class II 21 CFR 870.1250 (DQY)

Recommendation – Additional information request from a microbiology standpoint

Purpose of Submission: would like to introduce the modified Catheter into interstate commerce.

Predicate Device

K082385 Chaperon Guiding Catheter, MicroVention, Inc

Device Description

The SOFIA™ Distal Access Catheter is a single-lumen, flexible catheter designed with coil and braid reinforcement. The distal segment is steam-shapeable and it has a hydrophilic coating for navigation through the vasculature. The radiopaque marker is located at the distal end of the catheter for visualization under fluoroscopy. An introducer sheath and shaping mandrel are also provided.

Indications for Use

*The SOFIA™ Distal Access Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA™ Distal Access Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. The SOFIA™ Distal Access Catheter is not intended for use in coronary arteries.*

Reviewer Comments

The Indications for Use are the identical to that of the predicate device and are as follows:



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

## Comparison to Predicate Device

| | **Chaperon Guiding Catheter – K082385 (Outer catheter)** | **SOFIA Distal Access Catheter** |
|---|---|---|
| Intended Use | Intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries. | Same |
| Material | Outer layer of polyester elastomer, stainless steel braid, inner liner of PTFE (polytetrafluoroehthylene).<br>Tungsten radiopaque marker, nylon hub, and polyester elastomer strain relief. | Outer layer of polyolefin elastomer, polyurethane elastomer , polyether block amide, polyamide; inner layer of PTFE/polyolefin; stainless steel braid and coil.<br>Pt/Ir radiopaque marker, nylon hub, polyurethane strain relief.<br>Pebax introducer sheath and stainless steel shaping mandrel. |
| Catheter size | 5F (Outer catheter) | Same |
| ID | 1.5 mm (0.059”) | 1.4 mm (0.055”) |
| OD | 1.7 mm (0.068”) | Same |
| Effective Length | Outer Catheter : 95 cm<br>Inner Catheter: 117 cm | 125 cm |
| Coating | Hydrophilic coating (inner catheter) | Hydrophilic coating (same as Headway Duo, K120917) |
| Tip Configuration | Preshaped | Steam shapeable by user |
| Guidewire compatibility | 0.035” or 0.038” | Same |
| Accessories | N/A | Introducer sheath and shaping mandrel (same as Headway Duo) |
| Packaging | Packaging Card/Tyvek pouch/Carton | Same, with dispenser tube to hold catheter on packaging card |
| Method of supply | Sterile and single use | Same |

(b)(4) Confidential and Proprietary Information and (b)(5)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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[redacted]



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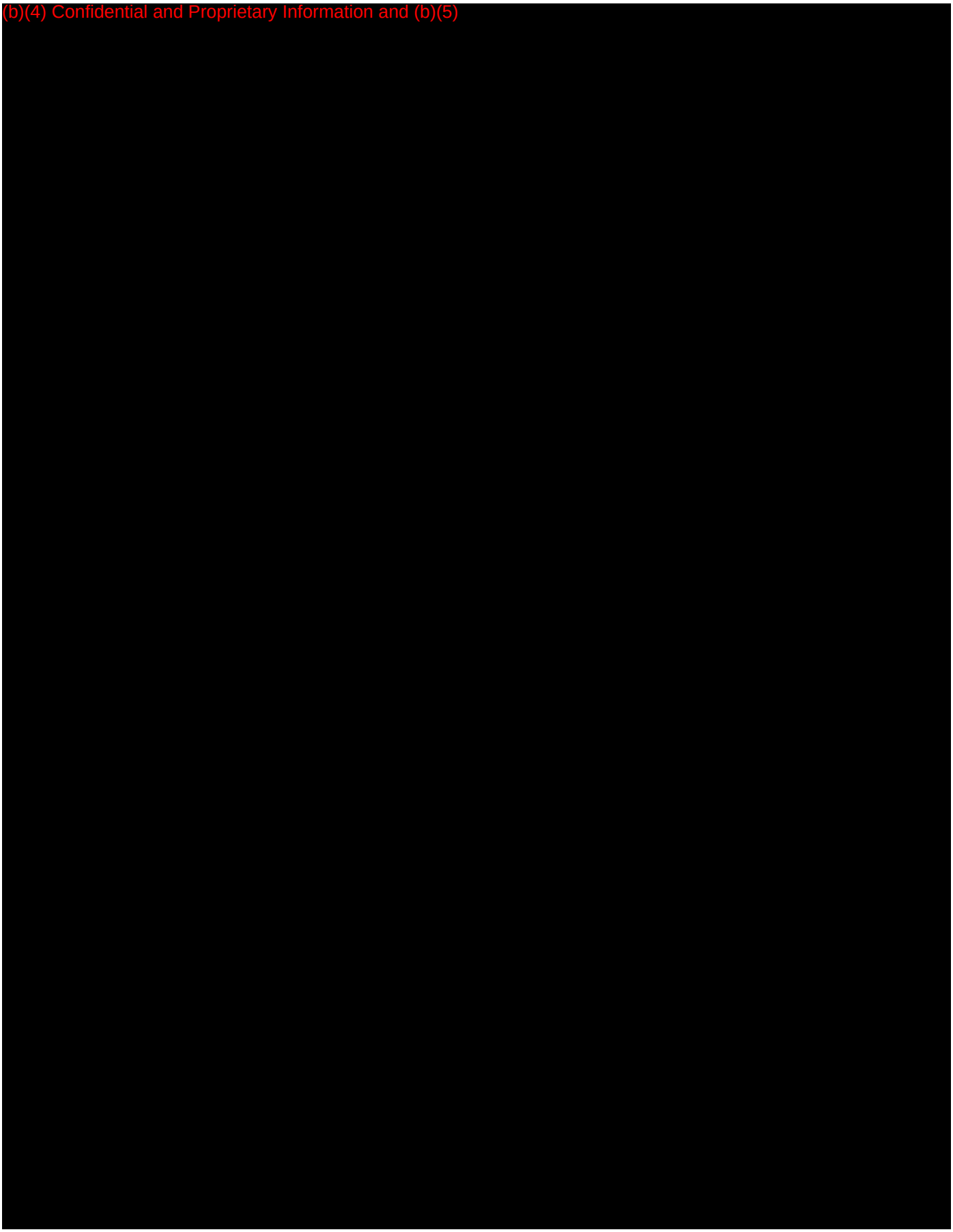

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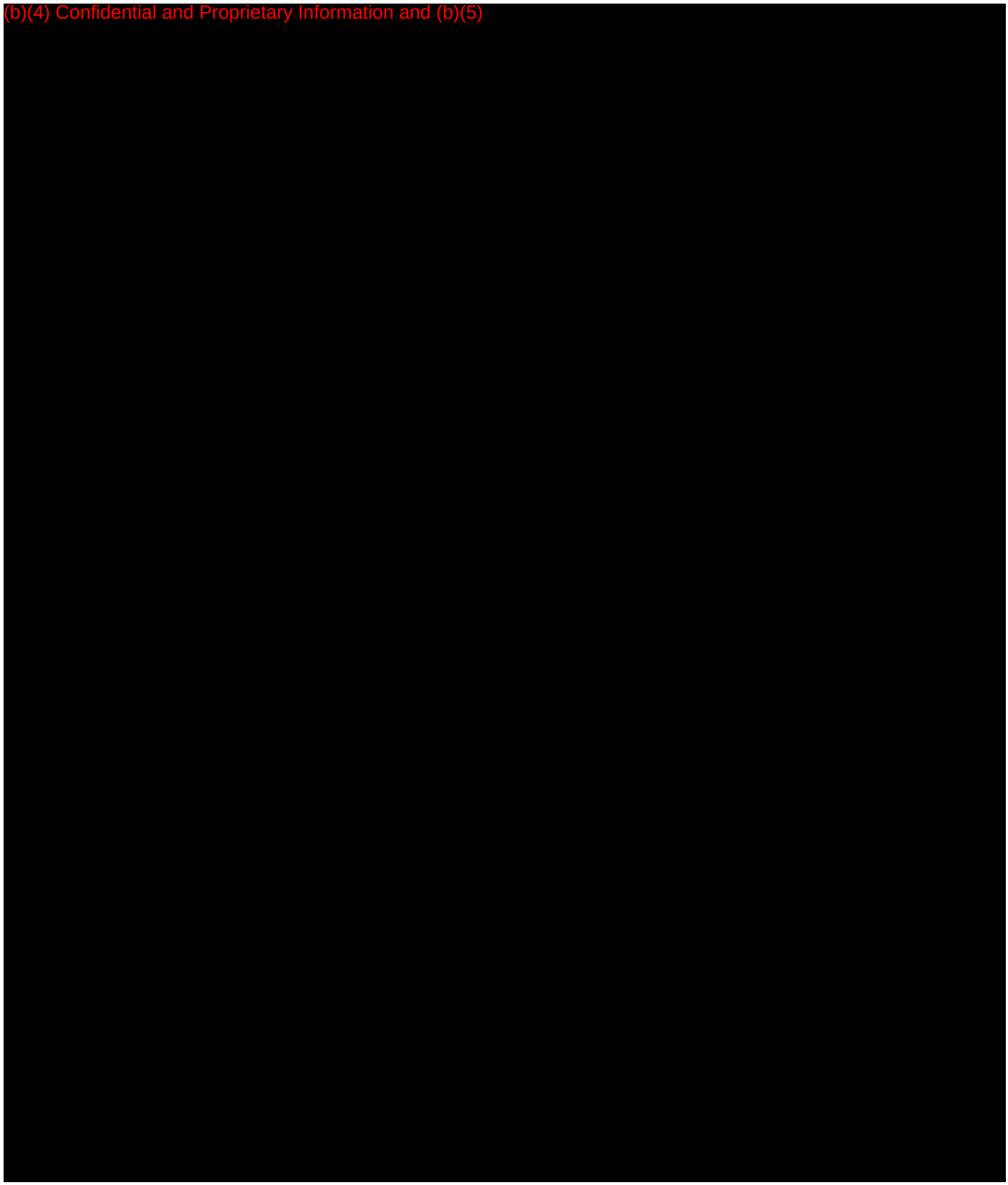



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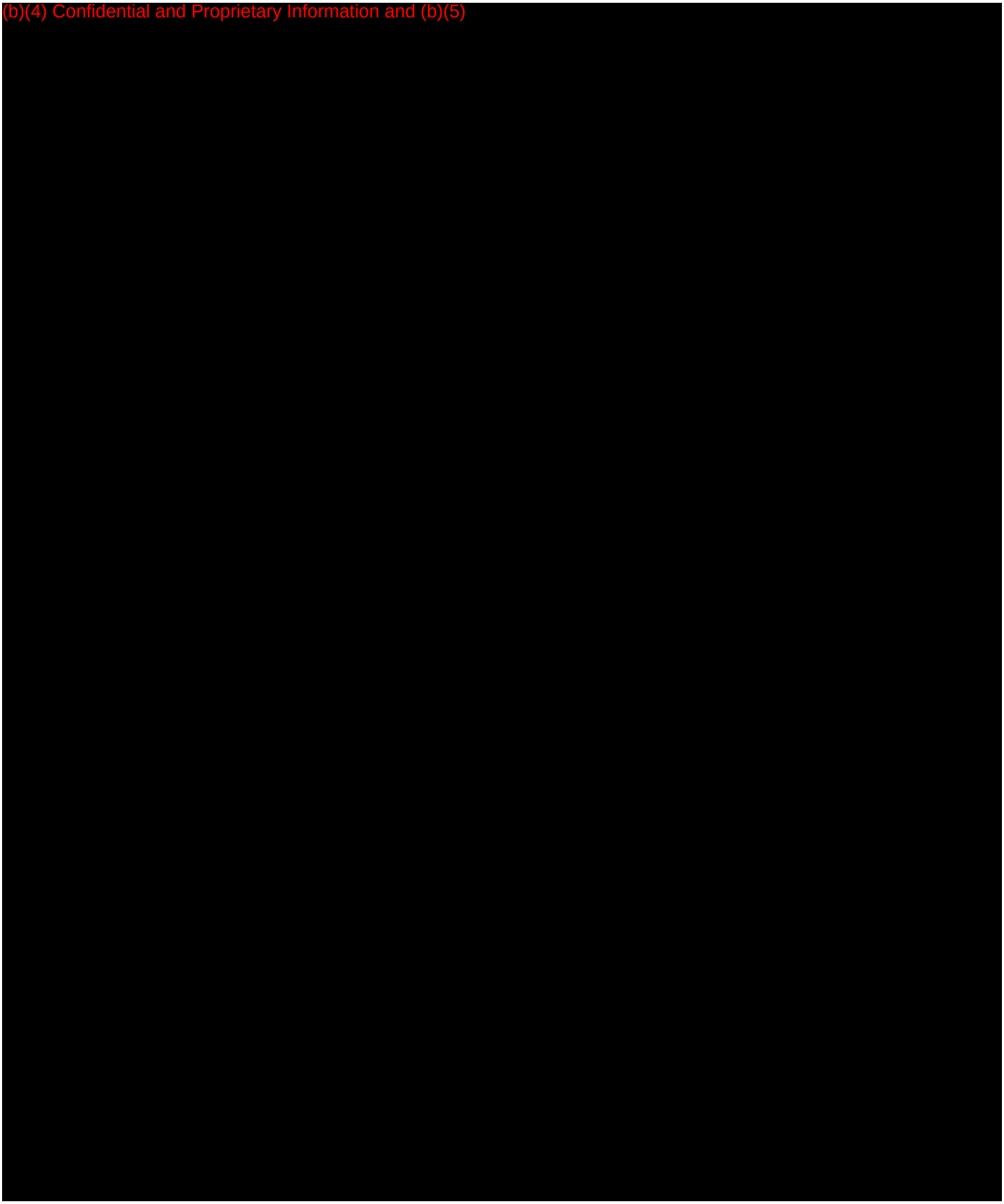



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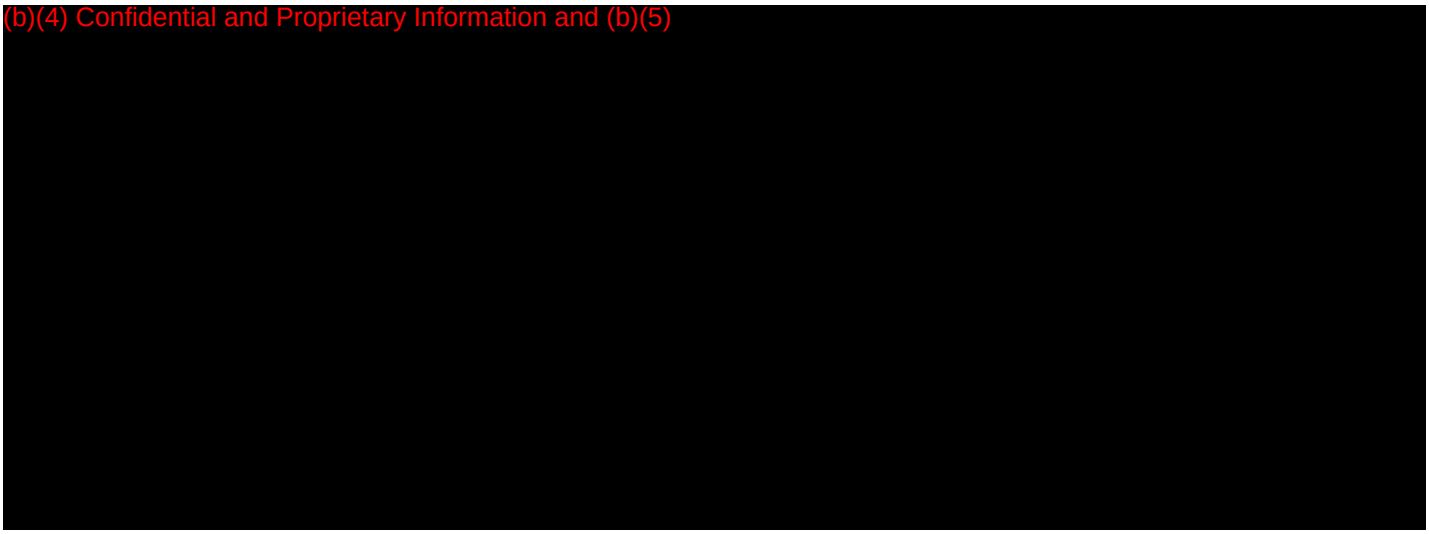



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**DEPARTMENT OF HEALTH AND HUMAN SERVICES** **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**Premarket Notification [510(k)] Review**
**Traditional/Abbreviated**

# K131482/S001

Date: August 8, 2013
To: The Record
From: Samuel Shimp, Ph.D.

Office: ODE
Division: DNPMD/NNDB

510(k) Holder: MicroVention, Inc.
Device Name: SOFIA Distal Access Catheter
Contact: Naomi Gong
Phone: (714) 247-8055
Fax: (714) 247-8014
Email: Naomi.Gong@microvention.com

| Reviewer Text | *Sponsor Text* | ***Comments*** |
|---|---|---|

**RECOMMENDATION: TELEPHONE HOLD (TH) and request additional information.**

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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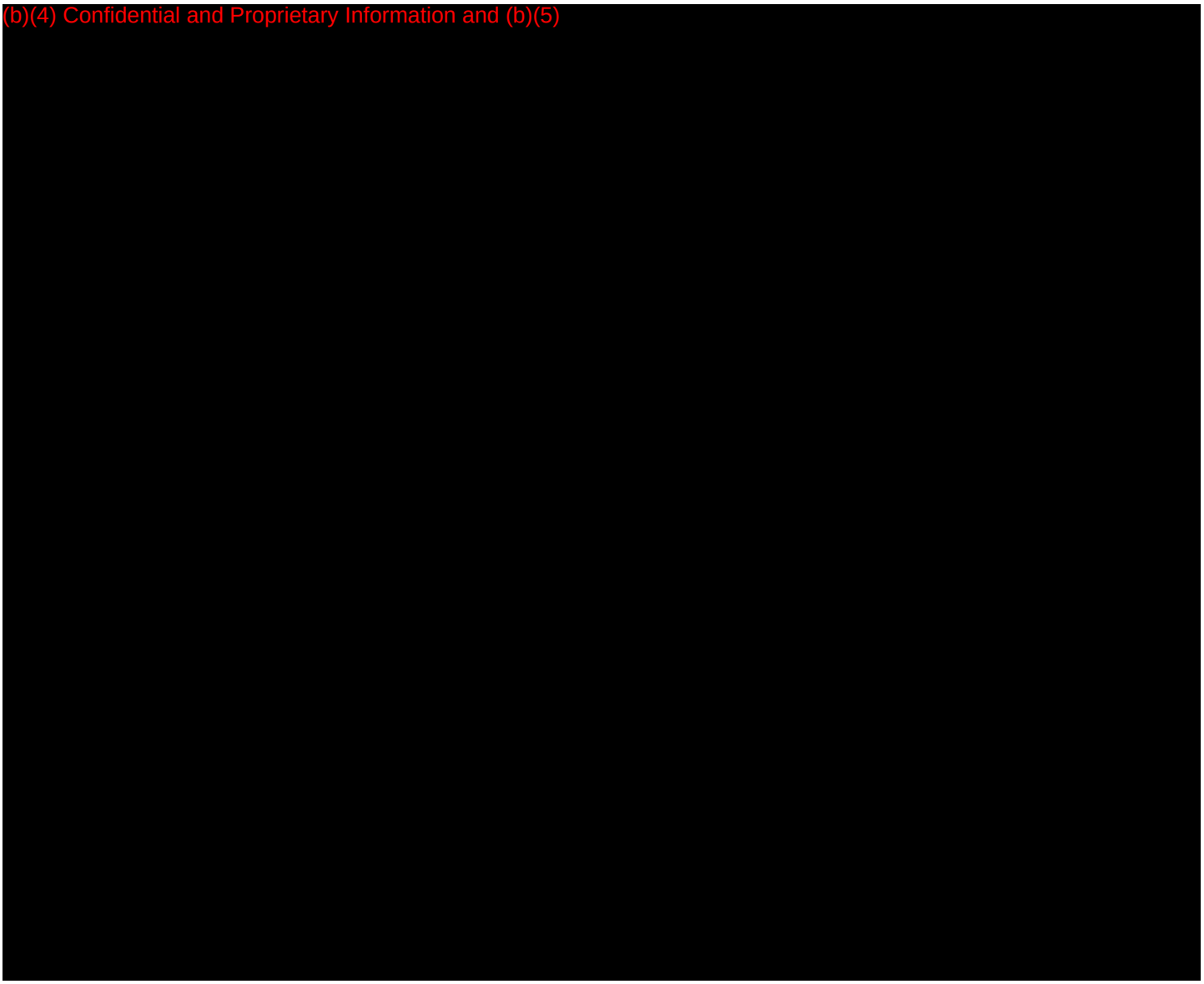


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| Intended Use | Intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries. | Same |
| Material | Outer layer of polyester elastomer, stainless steel braid, inner liner of PTFE (polytetrafluoroehthylene).<br>Tungsten radiopaque marker, nylon hub, and polyester elastomer strain relief. | Outer layer of polyolefin elastomer, polyurethane elastomer , polyether block amide, polyamide; inner layer of PTFE/polyolefin; stainless steel braid and coil.<br>Pt/Ir radiopaque marker, nylon hub, polyurethane strain relief.<br>Pebax introducer sheath and stainless steel shaping mandrel. |
| Catheter size | 5F (Outer catheter) | Same |
| ID | 1.5 mm (0.059") | 1.4 mm (0.055") |
| OD | 1.7 mm (0.068") | Same |
| Effective Length | Outer Catheter : 95 cm<br>Inner Catheter: 117 cm | 125 cm |
| Coating | Hydrophilic coating (inner catheter) | Hydrophilic coating (same as Headway Duo, K120917) |
| Tip Configuration | Preshaped | Steam shapeable by user |
| Guidewire compatibility | 0.035" or 0.038" | Same |
| Accessories | N/A | Introducer sheath and shaping mandrel (same as Headway Duo) |
| Packaging | Packaging Card/Tyvek pouch/Carton | Same, with dispenser tube to hold catheter on packaging card |
| Method of supply | Sterile and single use | Same |

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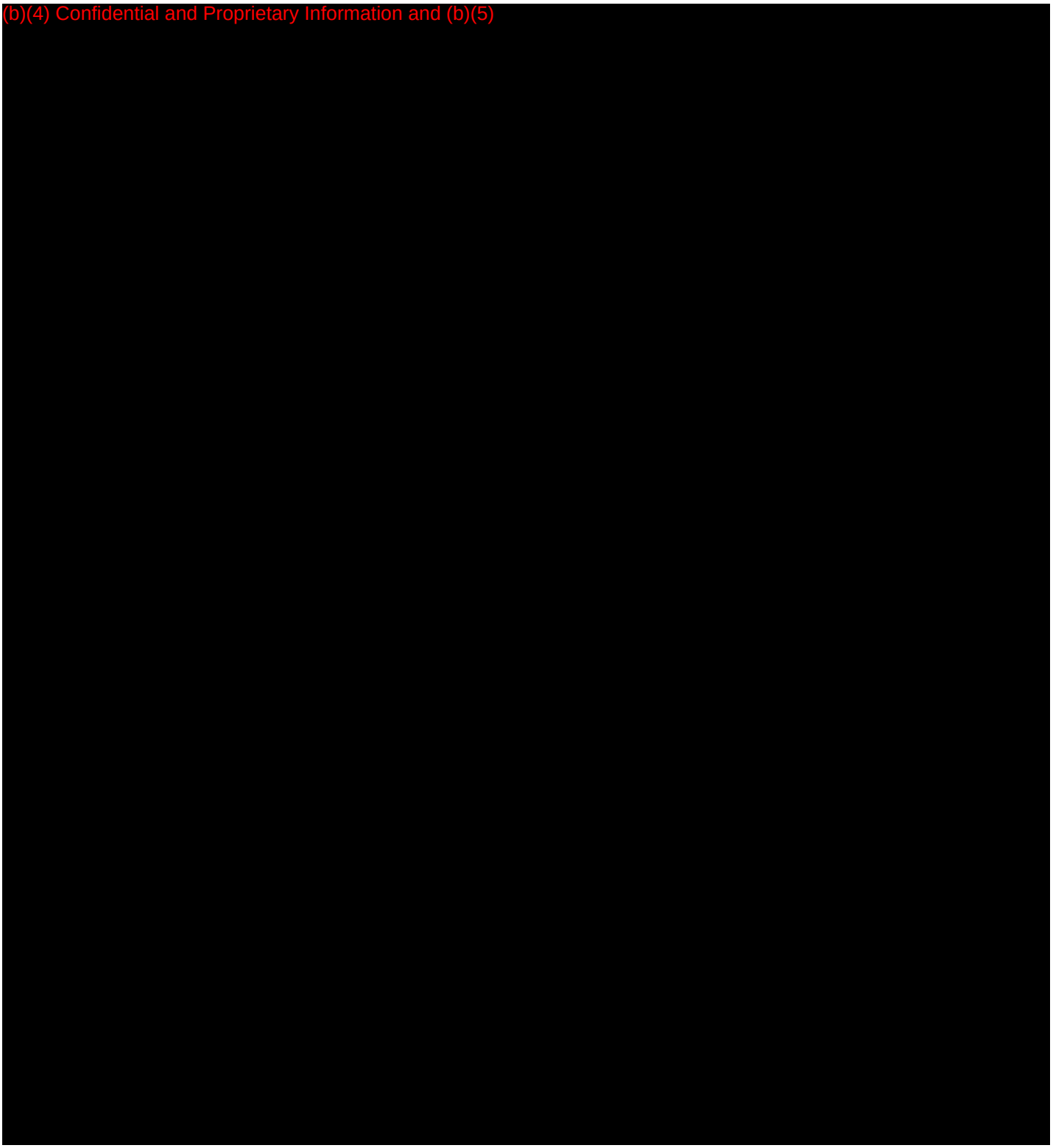


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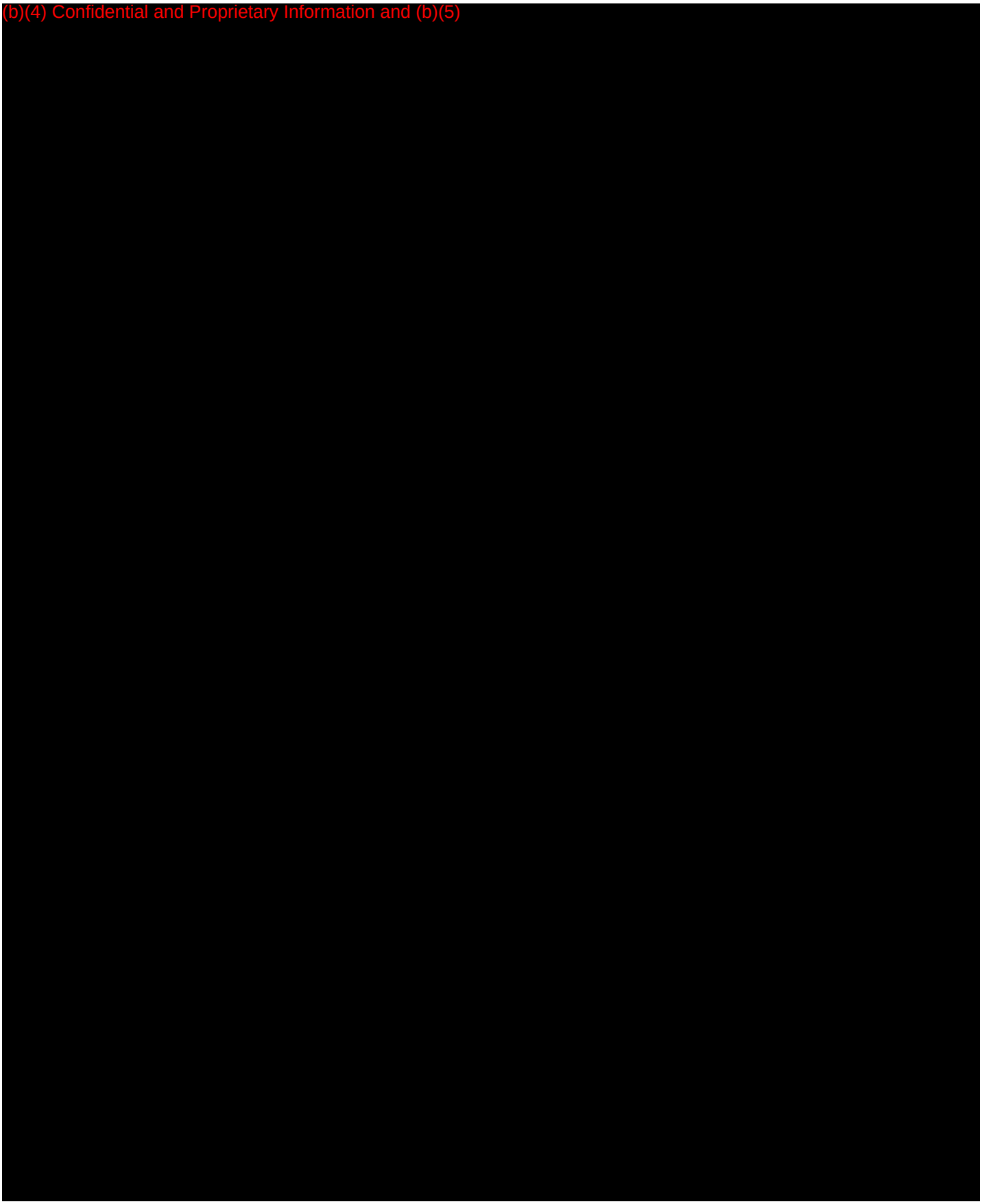


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(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

| Digital Signature Concurrence Table | |
|---|---|
| Reviewer Sign-Off | |
| Branch Chief Sign-Off (optional) | |
| Division Sign-Off (optional) | |


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

# MEMORANDUM

Date: November 13, 2013

From: Jeffrey Toy, Ph.D., Toxicologist

Subject: K131482/S001 MicroVention SOFIA Distal Access Catheter Biocompatibility Review

To: The Record

Through: Samuel Shimp, Ph.D.
Team Leader

---

**RECOMMENDATION: SUBSTANTIALLY EQUIVALENT**

**PURPOSE:**
MIcroVention request 510k clearance for their SOFIA Distal Access Catheter.

*Excerpted text is italicized*

**INDICATION FOR USE**
*The SOFIA Distal Access Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries.*

(b)(4) Confidential and Proprietary Information and (b)(5)


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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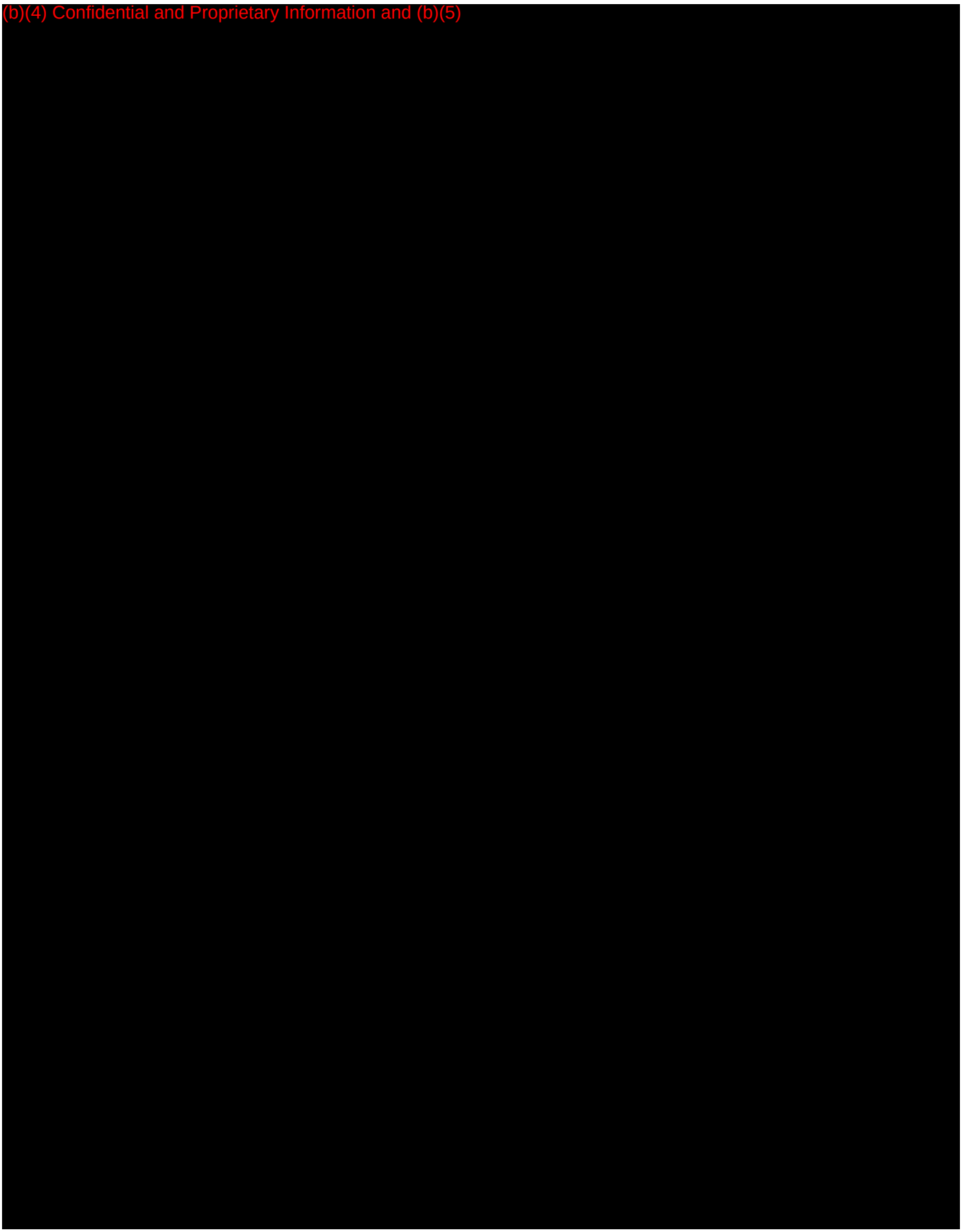


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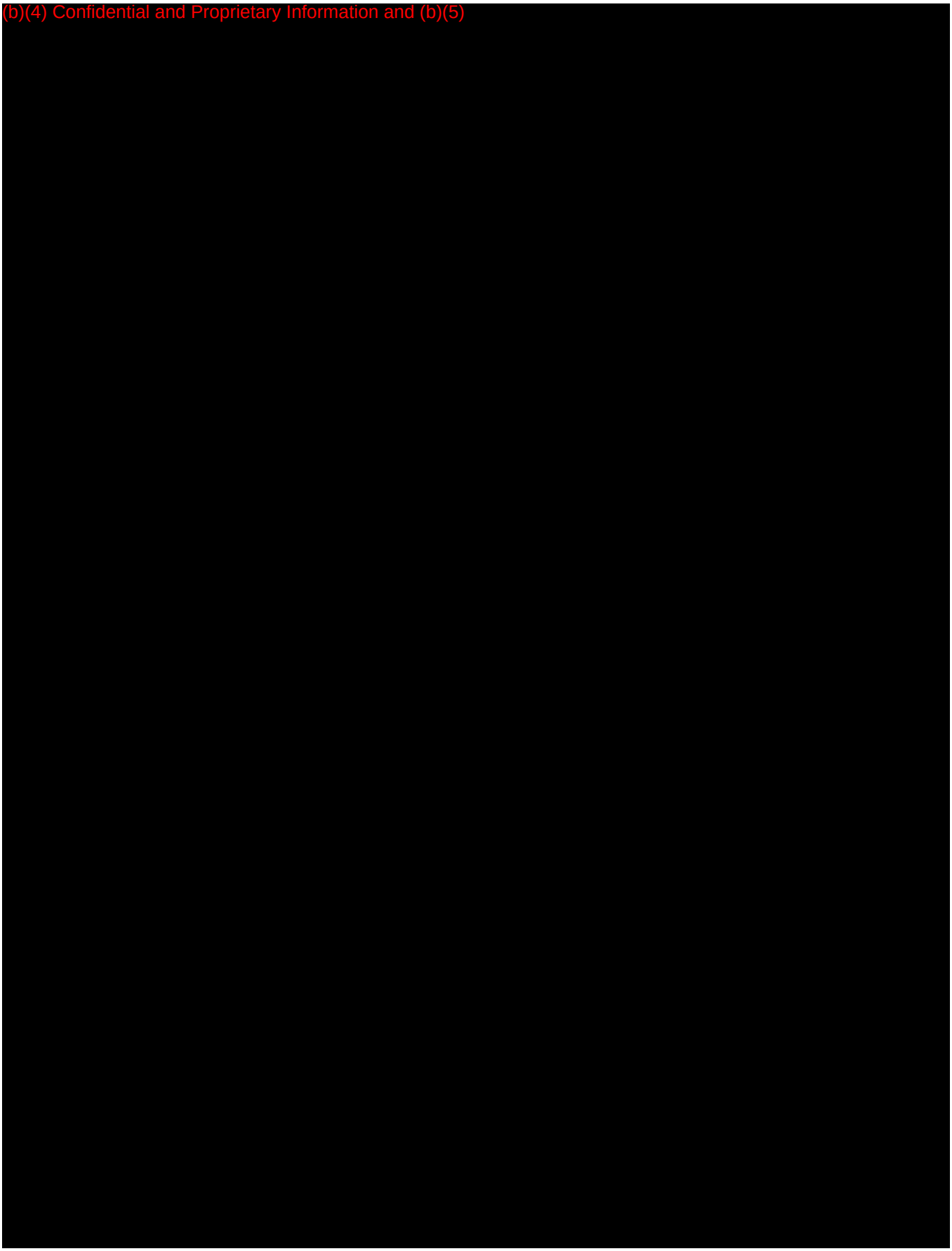


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[redacted]

## RECOMMENDATION: SUBSTANTIALLY EQUIVALENT

| | |
|---|---|
| **Reviewer Sign-Off:** | |


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

Date: November 18, 2013

From: Myra Smith, DNPMD/NNDB

To: Samuel Shimp, Ph.D. DNPMD/NNDB

cc: The Record

Subject: K131482/S002 - Microbiology Review
Device Trade Name: SOFIA Distal Access Catheter
Sponsor: MicroVention Inc.

Classification

Generic Name: Percutaneous Catheter Classification:
Class II 21 CFR 870.1250 (DQY)

Recommendation –Substantial Equivalence (SE) from a microbiology standpoint

Purpose of Submission: would like to introduce the modified SOFIA Distal Access Catheter into interstate commerce.

(b)(4) Confidential and Proprietary Information



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information

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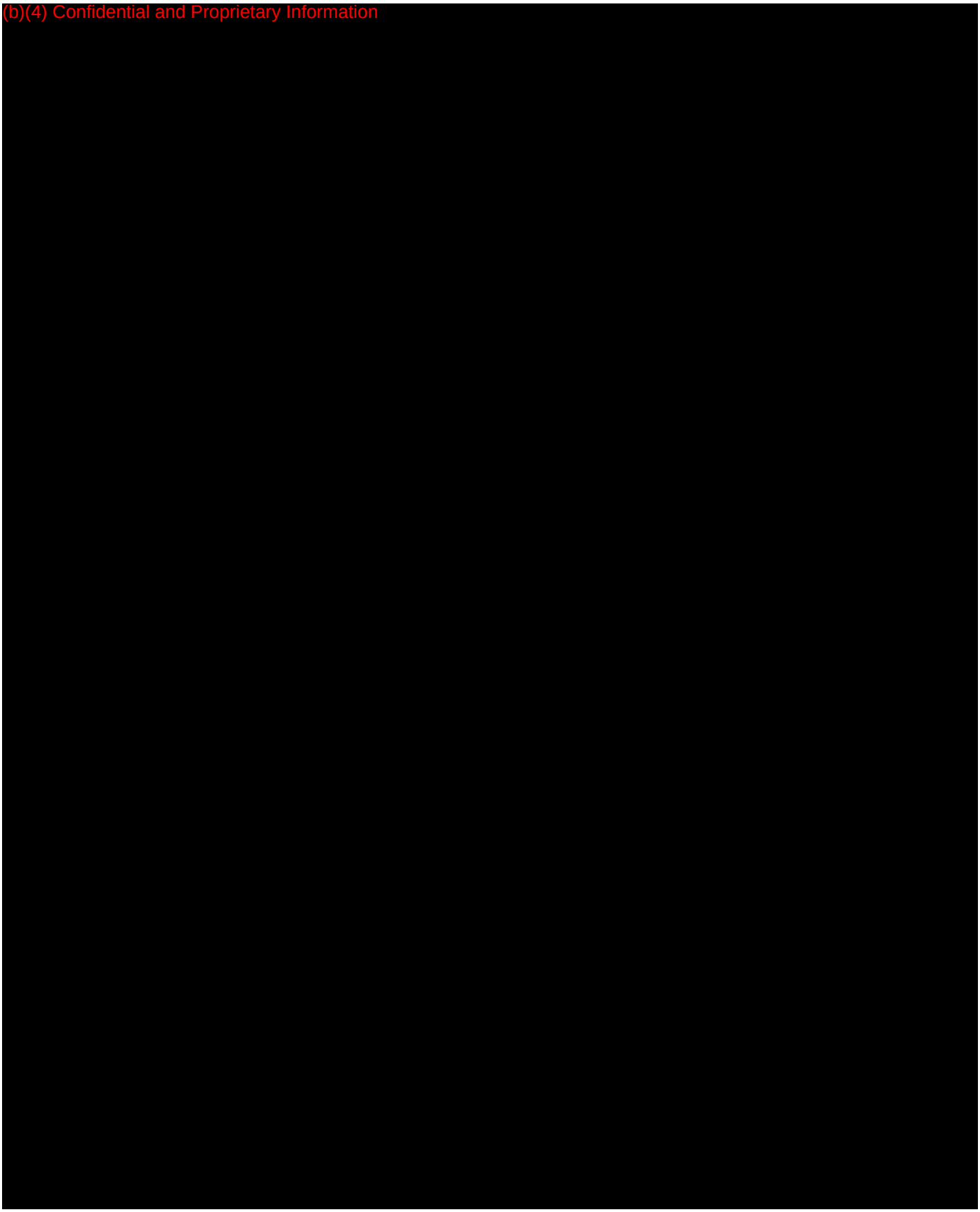
(b)(4) Confidential and Proprietary Information





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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[redacted]



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Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

Conclusion/Recommendation: Substantial Equivalence (SE) from a microbiology standpoint. MicroVention has addressed outstanding microbiology deficiencies.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES** **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**Premarket Notification [510(k)] Review**
**Traditional/Abbreviated**

# K131482/S002

Date: November 18, 2013
To: The Record
From: Samuel Shimp, Ph.D.

Office: ODE
Division: DNPMD/NNDB

510(k) Holder: MicroVention, Inc.
Device Name: SOFIA Distal Access Catheter
Contact: Naomi Gong
Phone: (714) 247-8055
Fax: (714) 247-8014
Email: Naomi.Gong@microvention.com

| Reviewer Text | *Sponsor Text* | ***Comments*** |
|---|---|---|

**RECOMMENDATION: SUBSTANTIALLY EQUIVALENT (SE): All deficiencies have been resolved and the performance testing, sterilization process, and biocompatibility data all support the SE determination.**

(b)(4) Confidential and Proprietary Information - (b)(5)

[redacted]


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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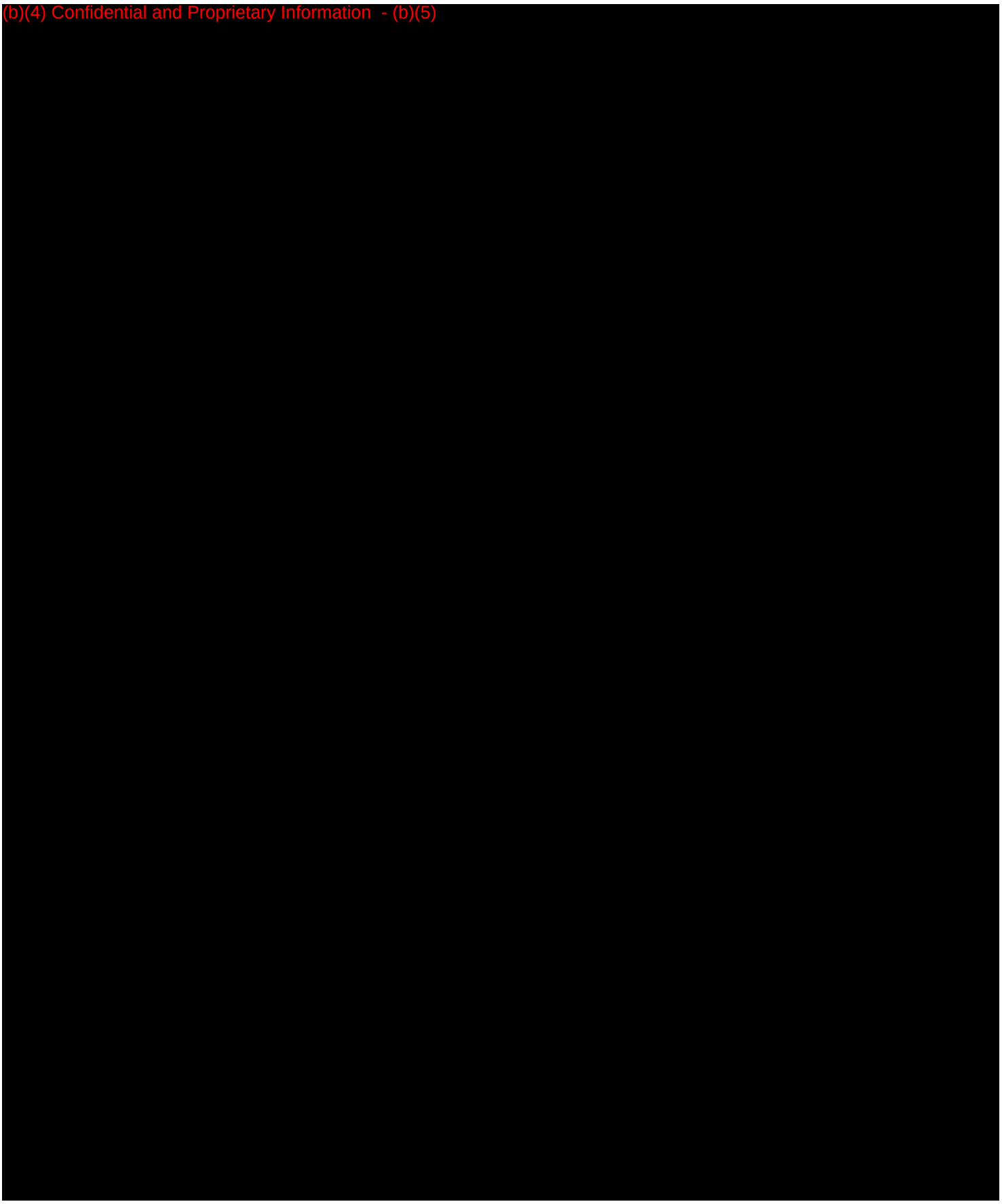



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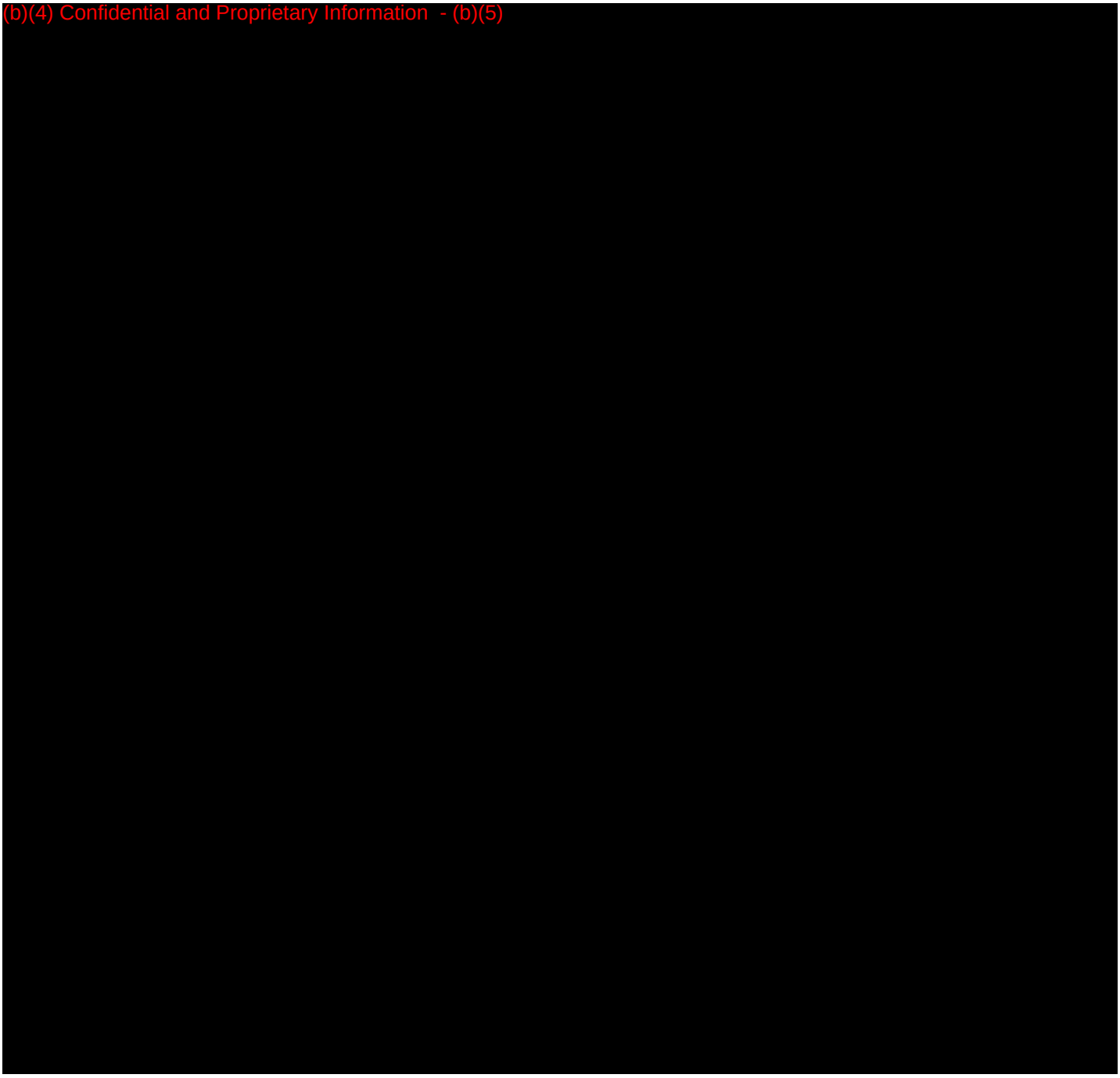



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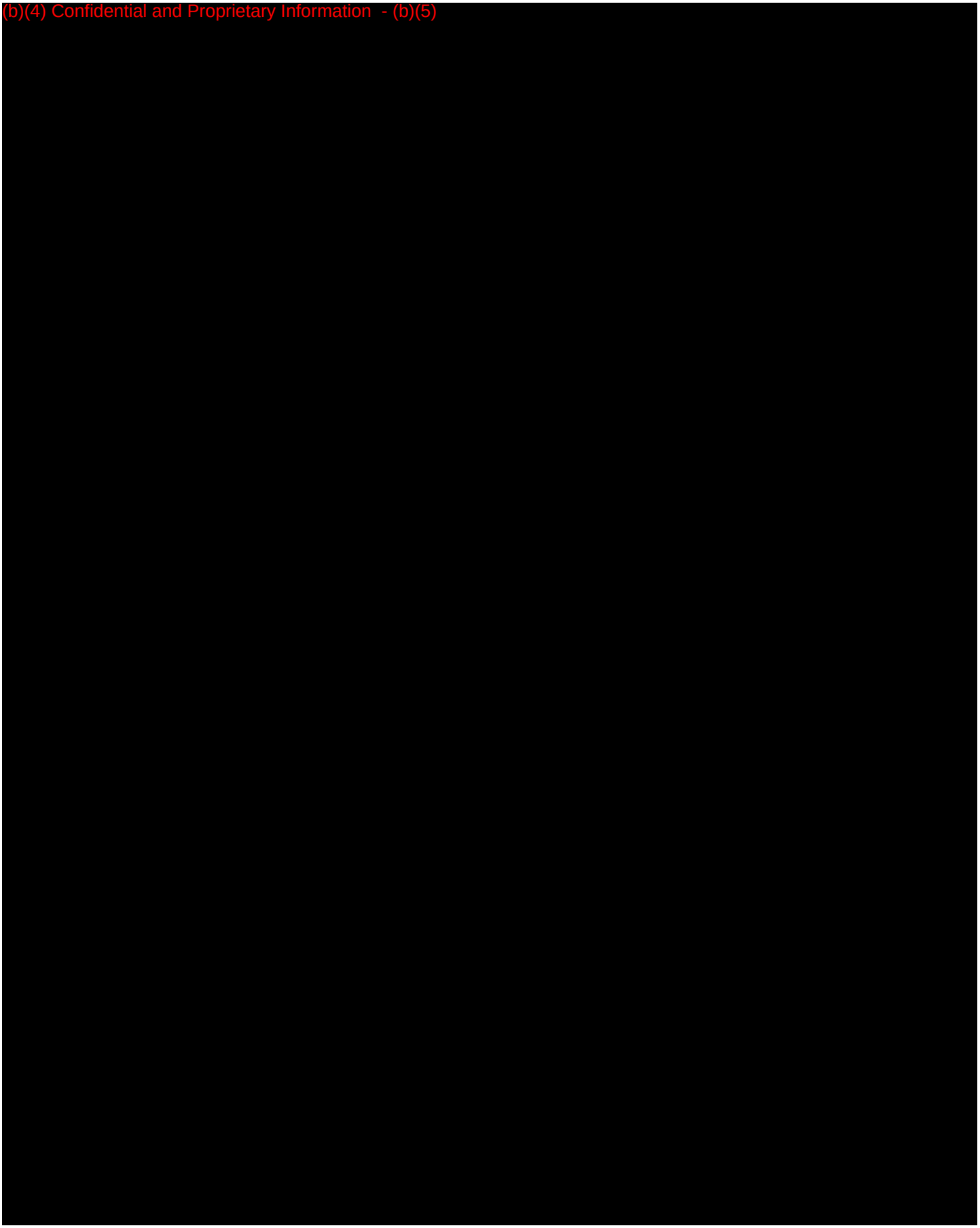



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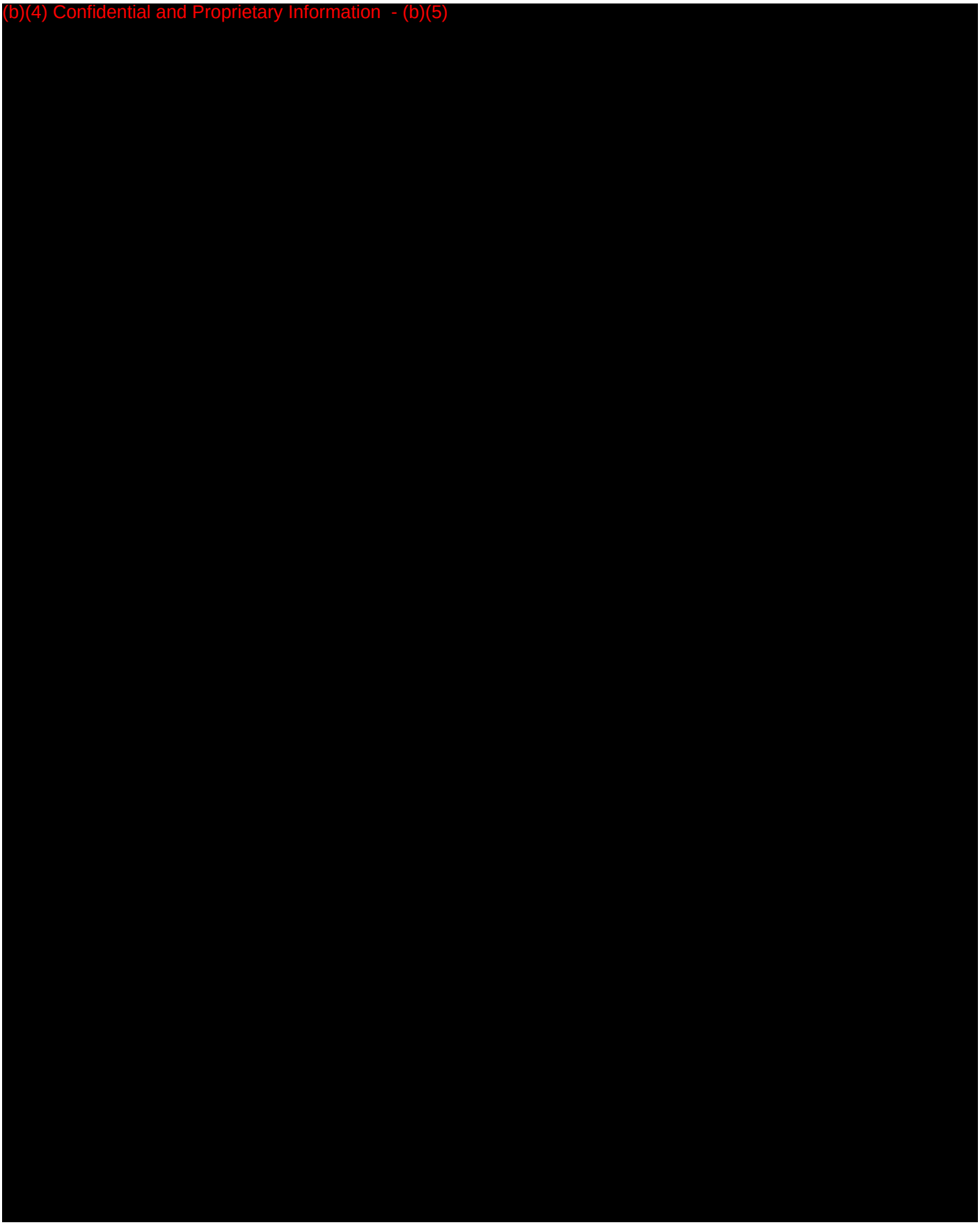



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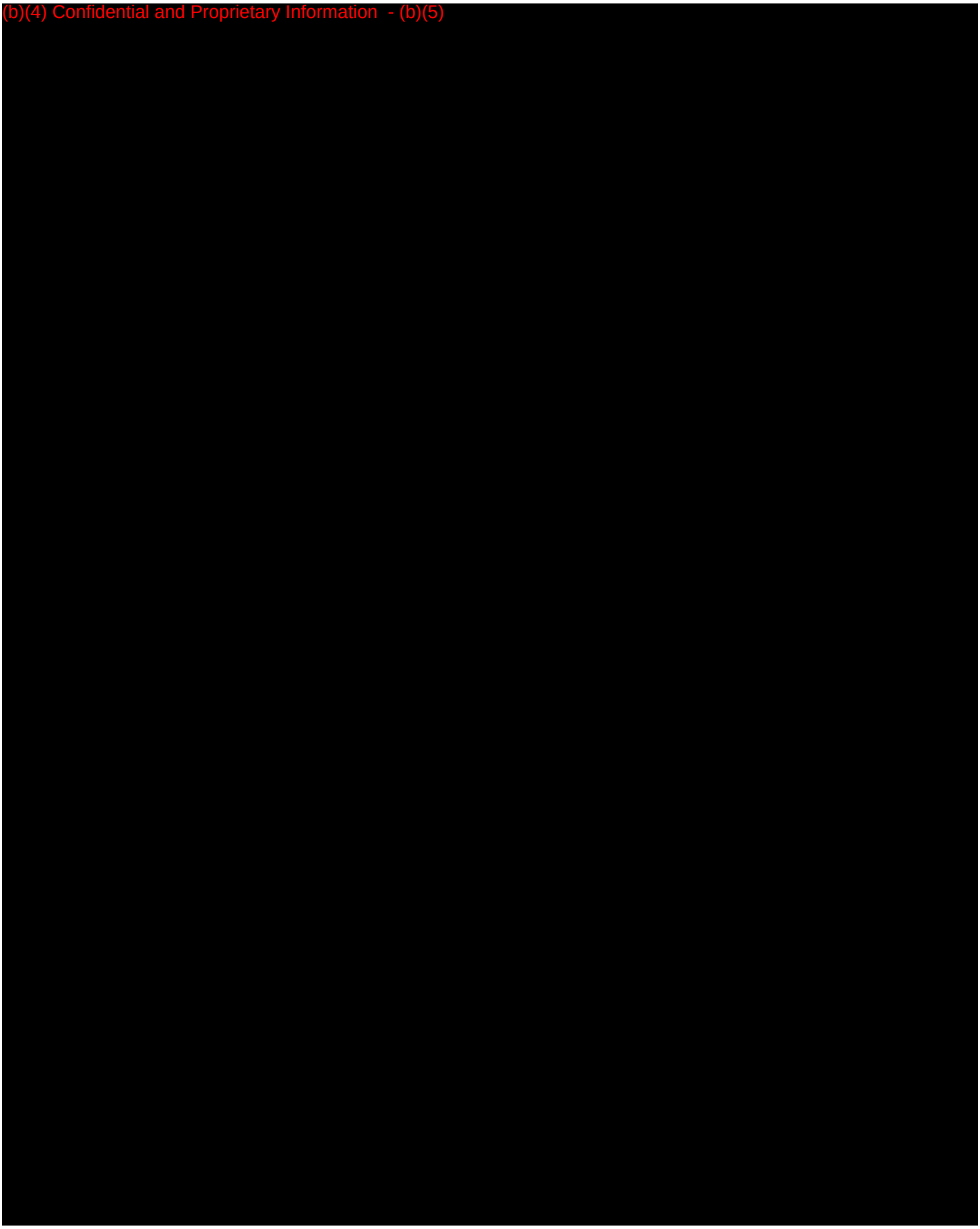



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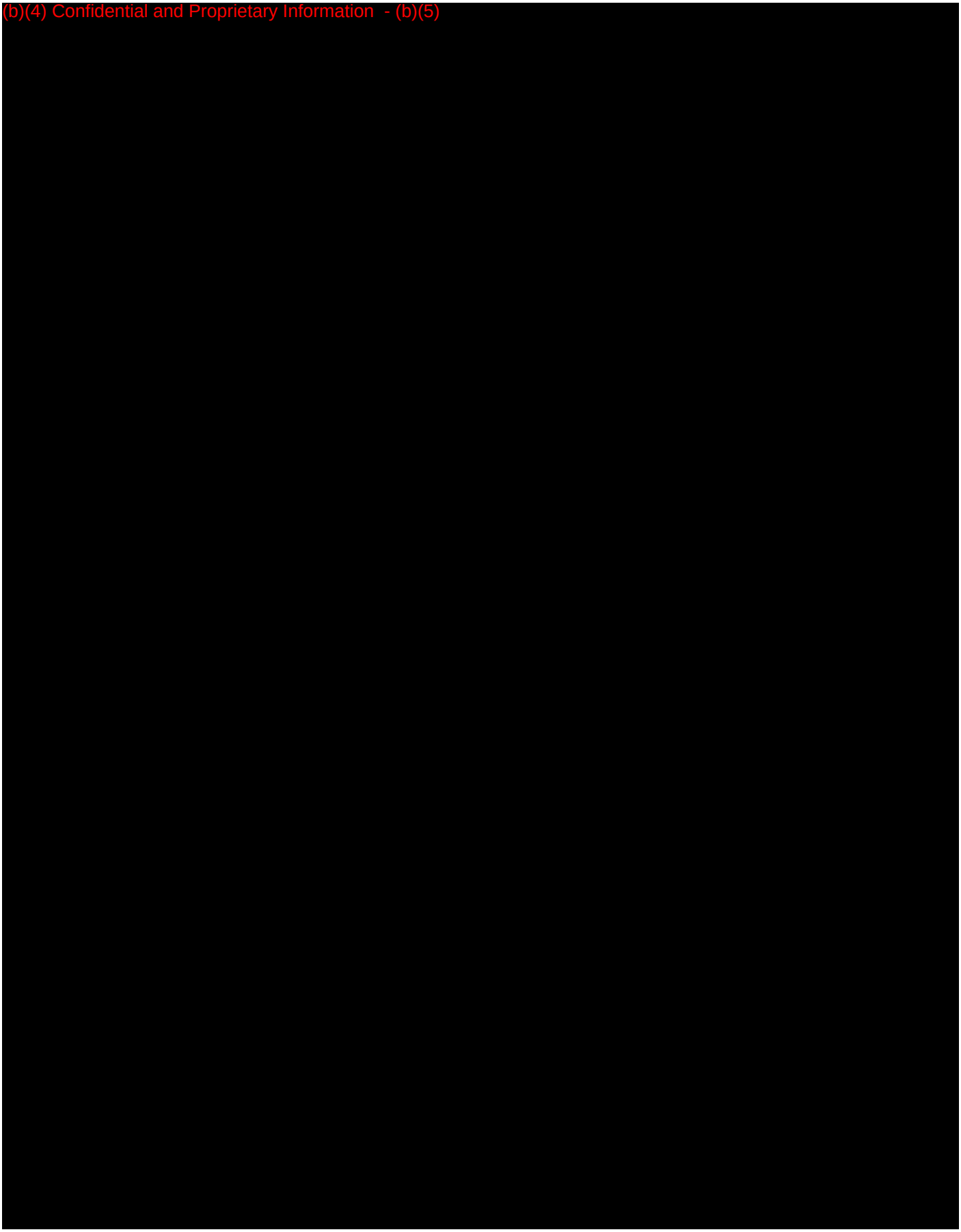



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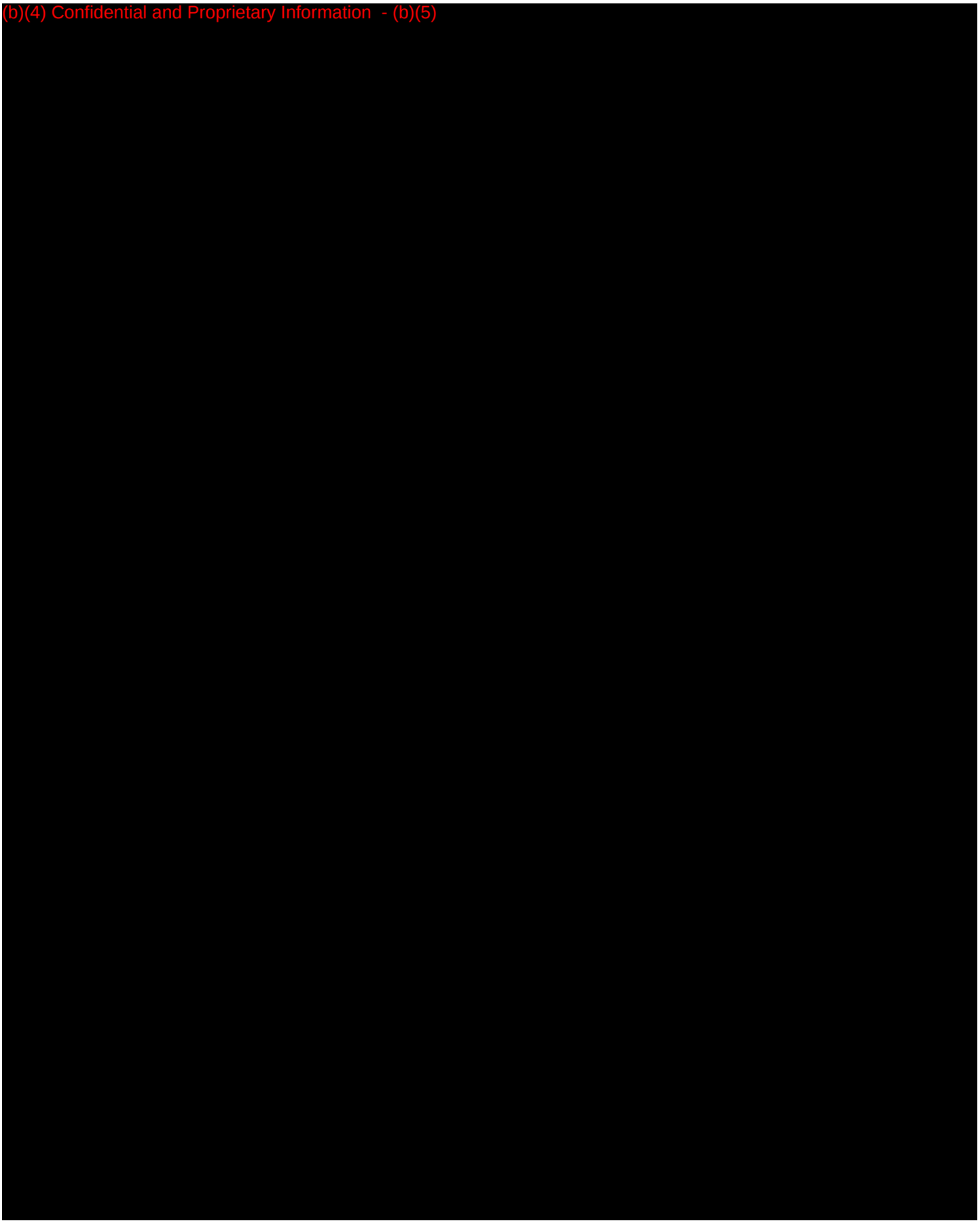



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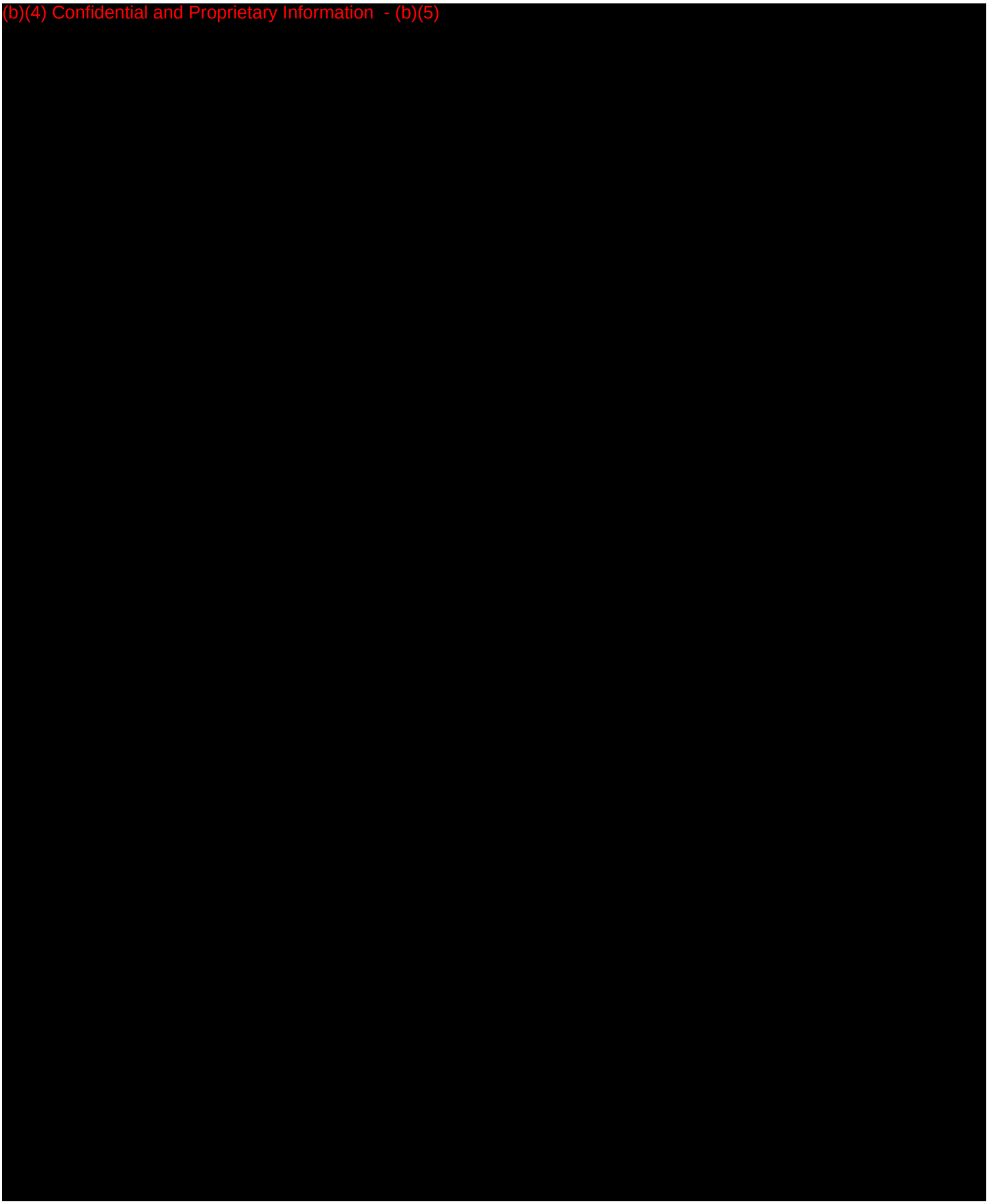



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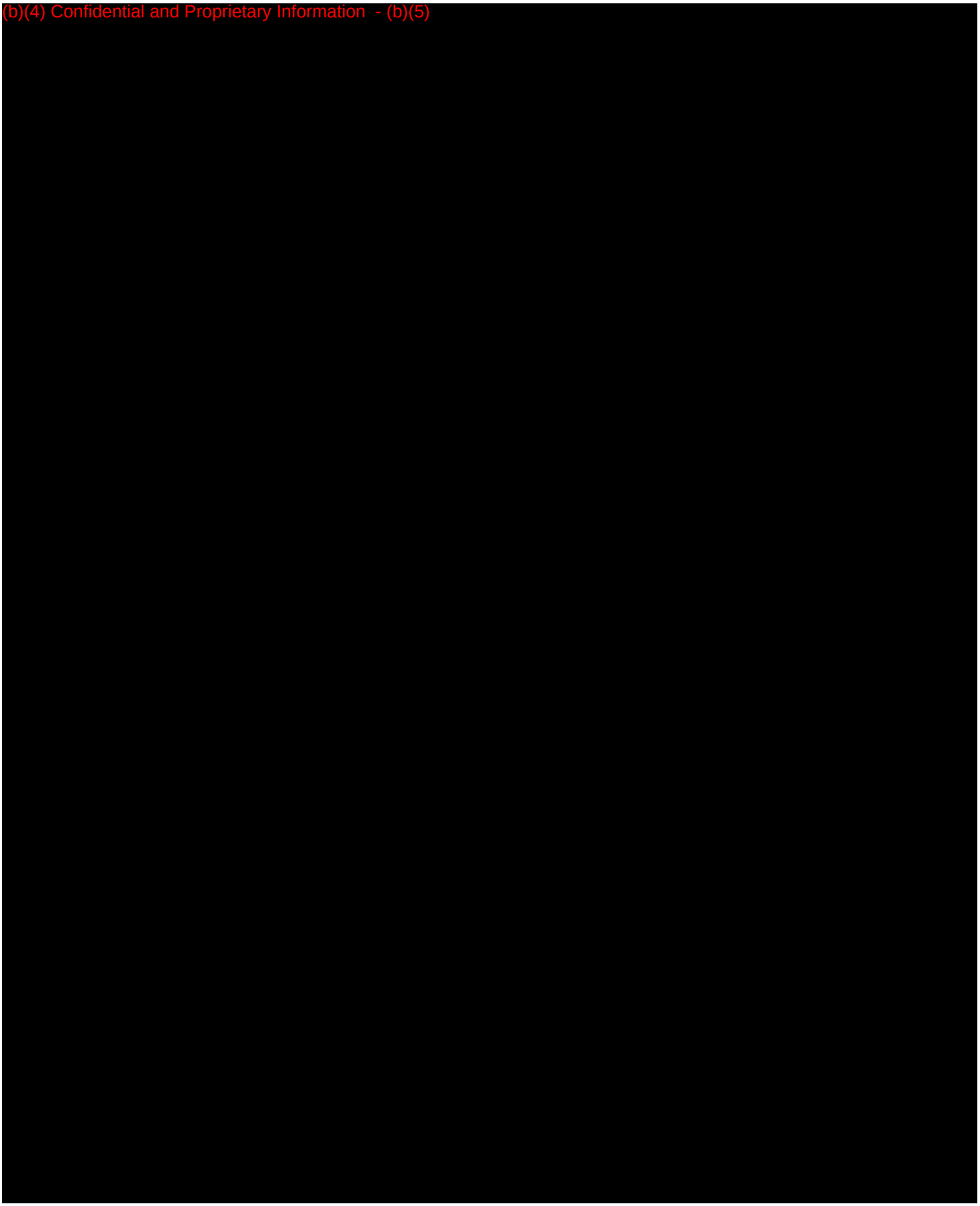



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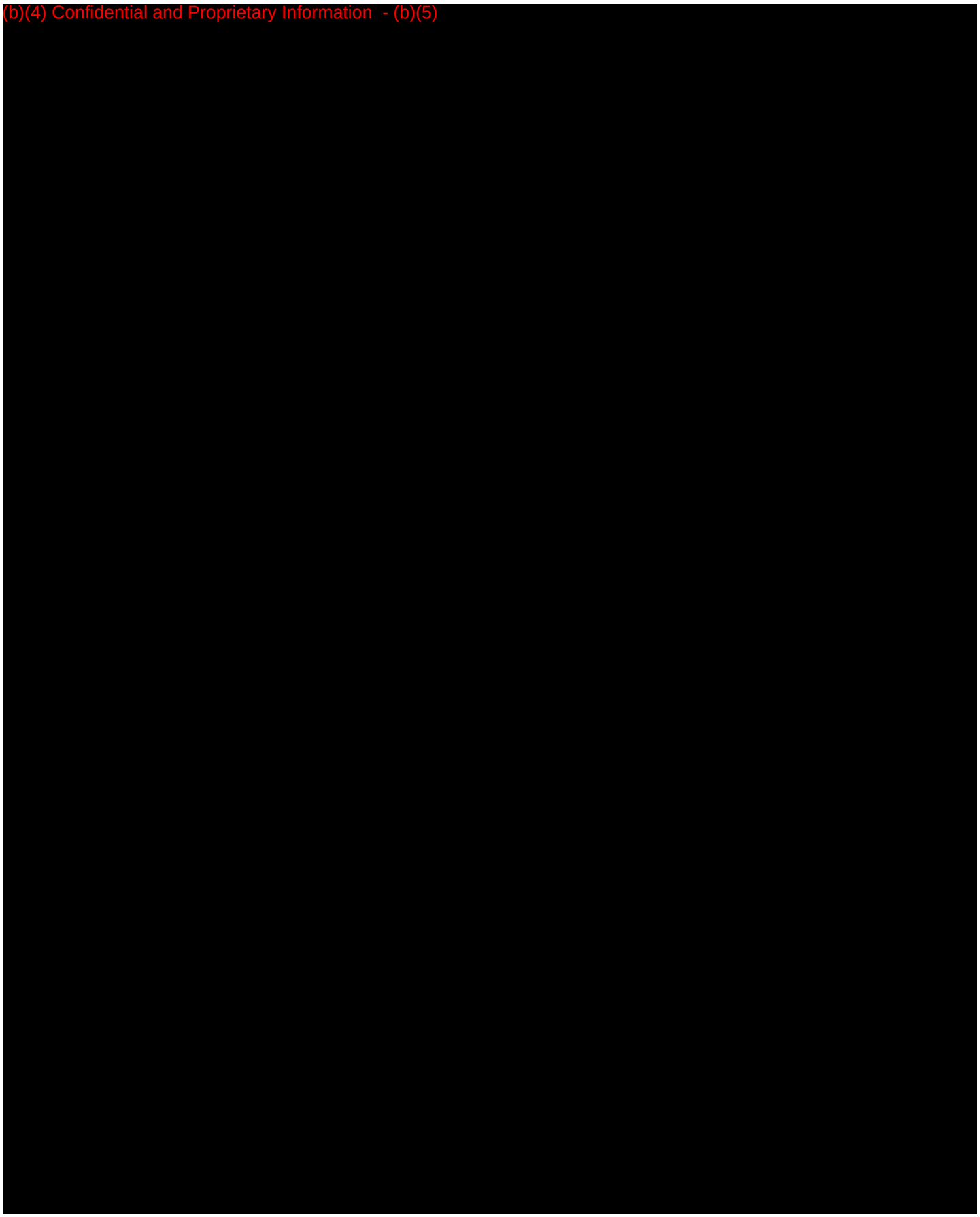



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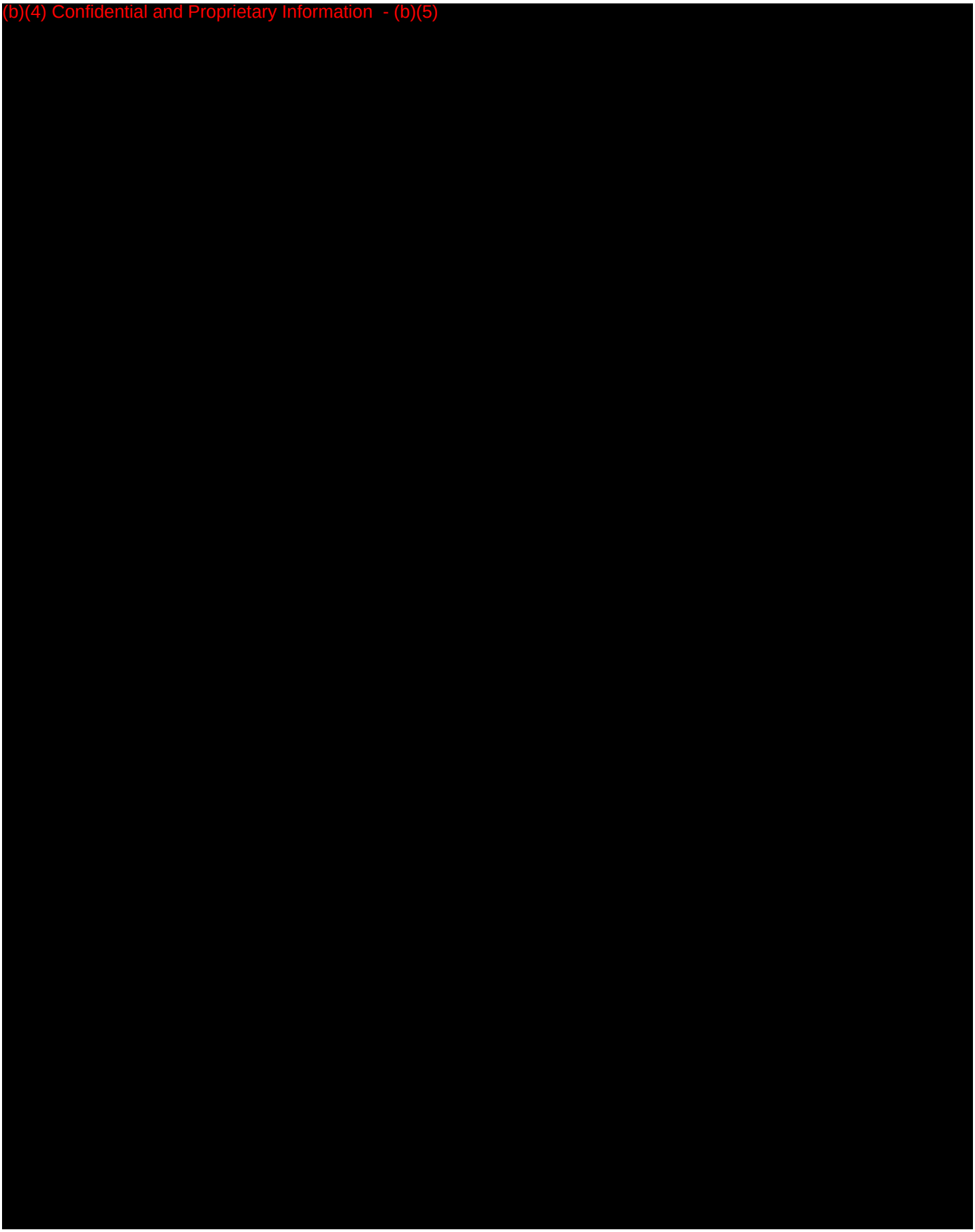



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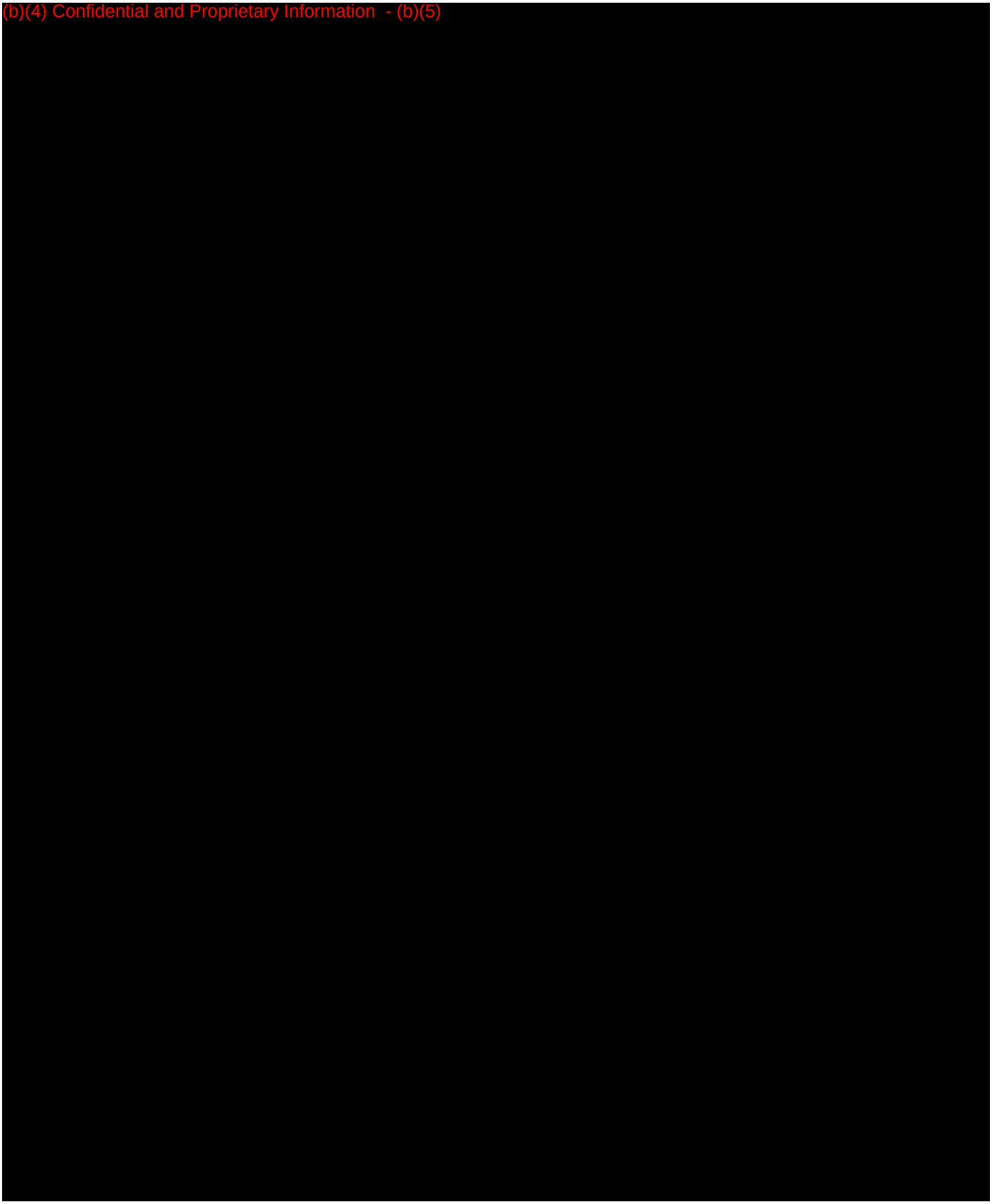



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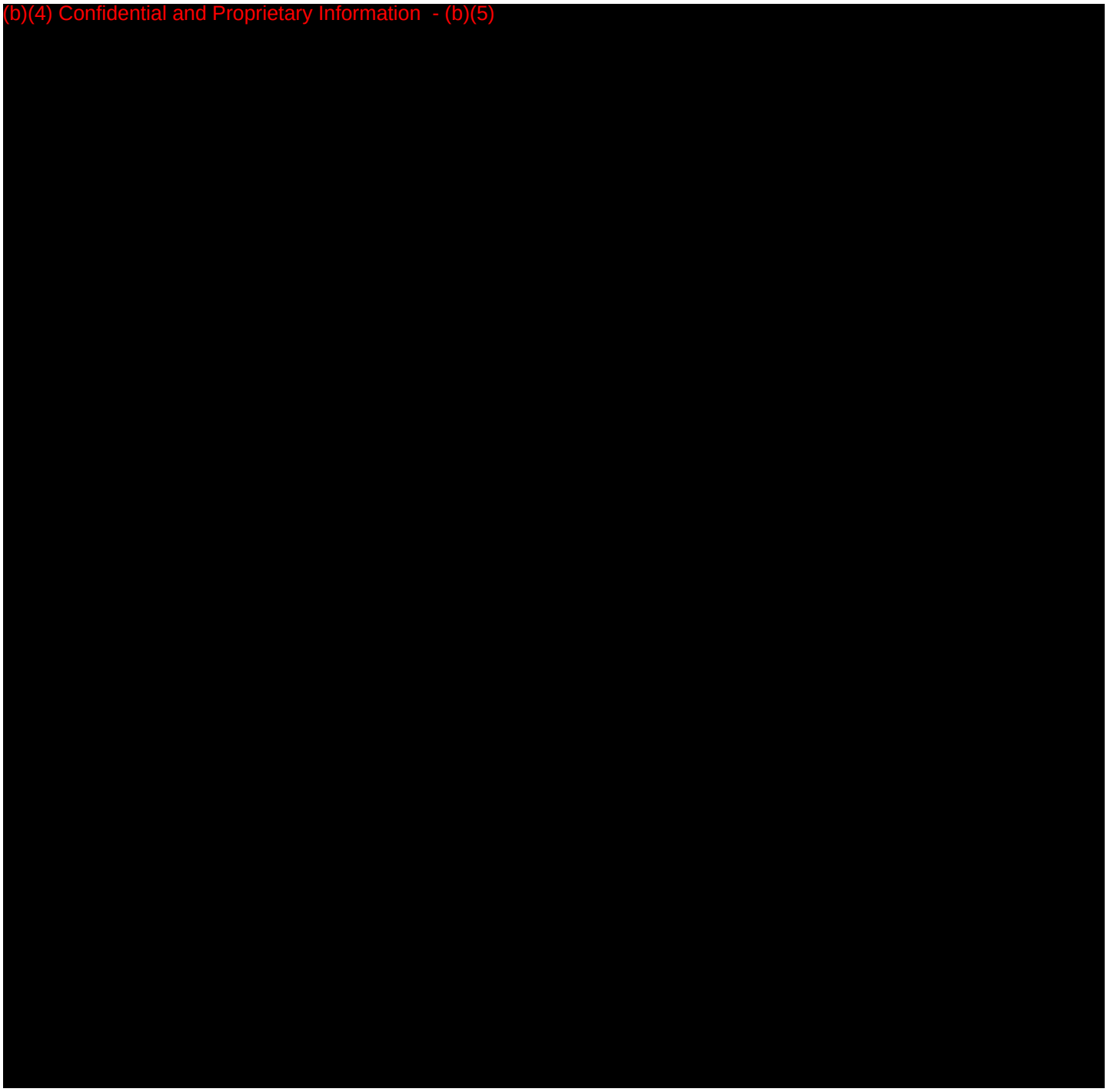



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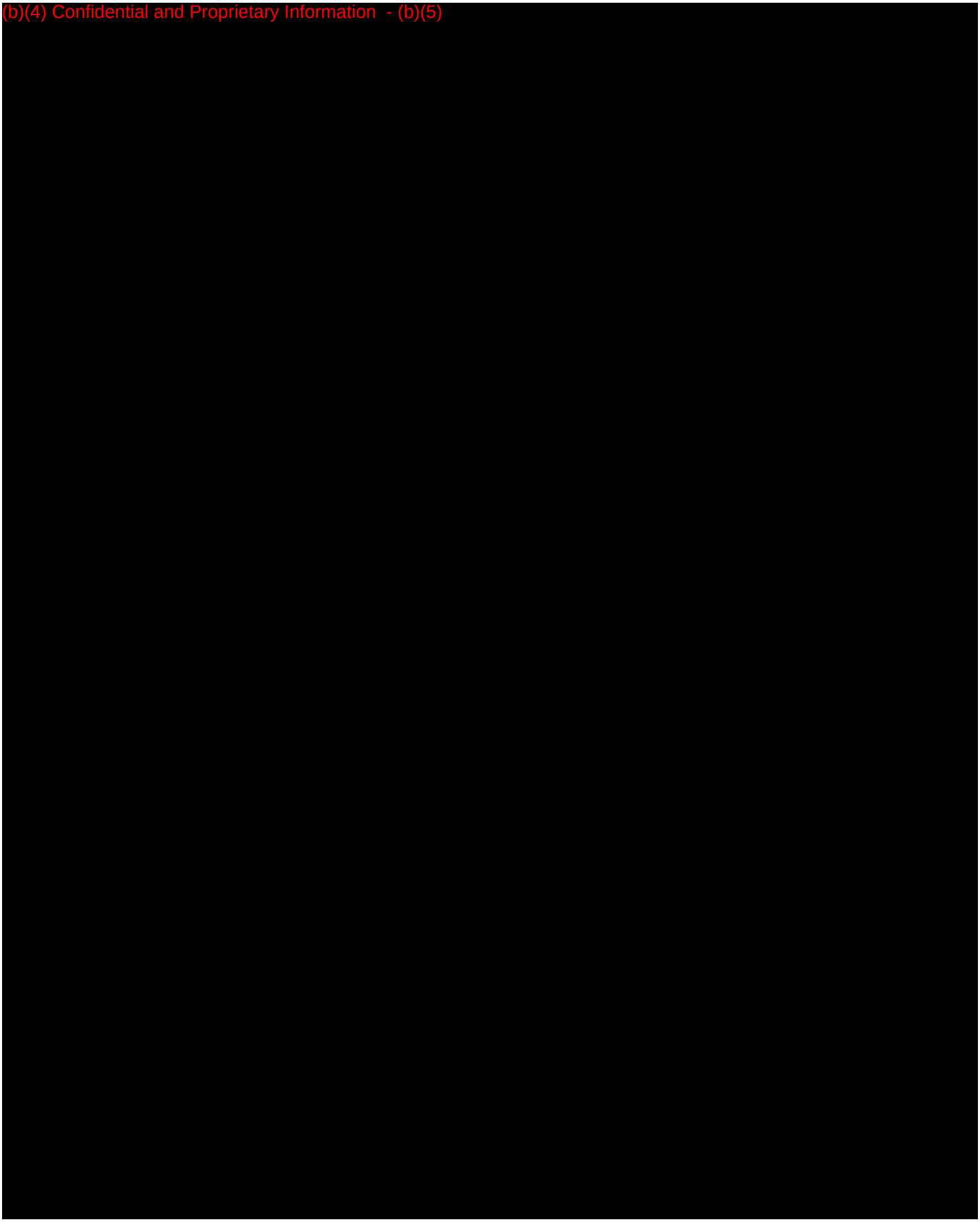



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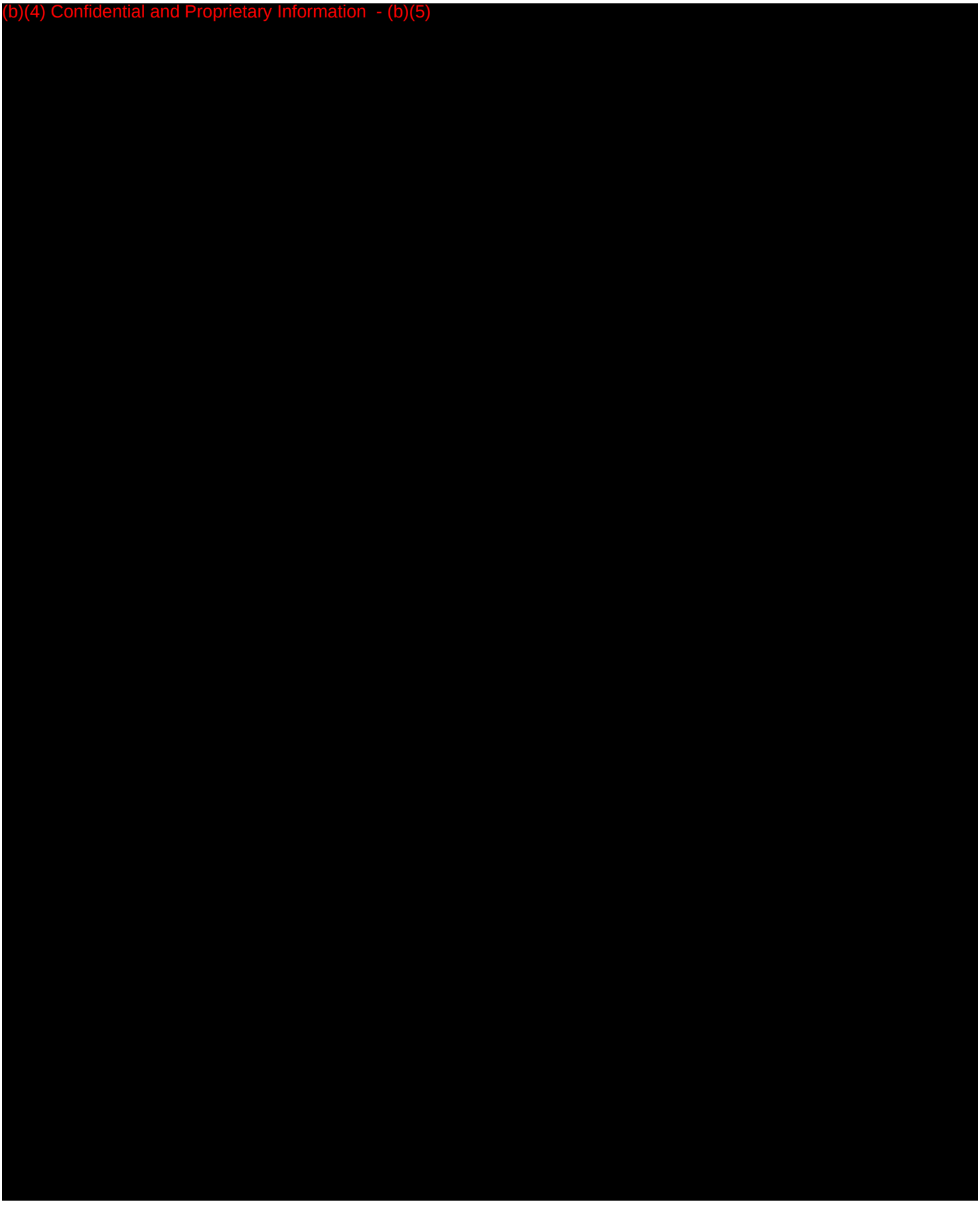



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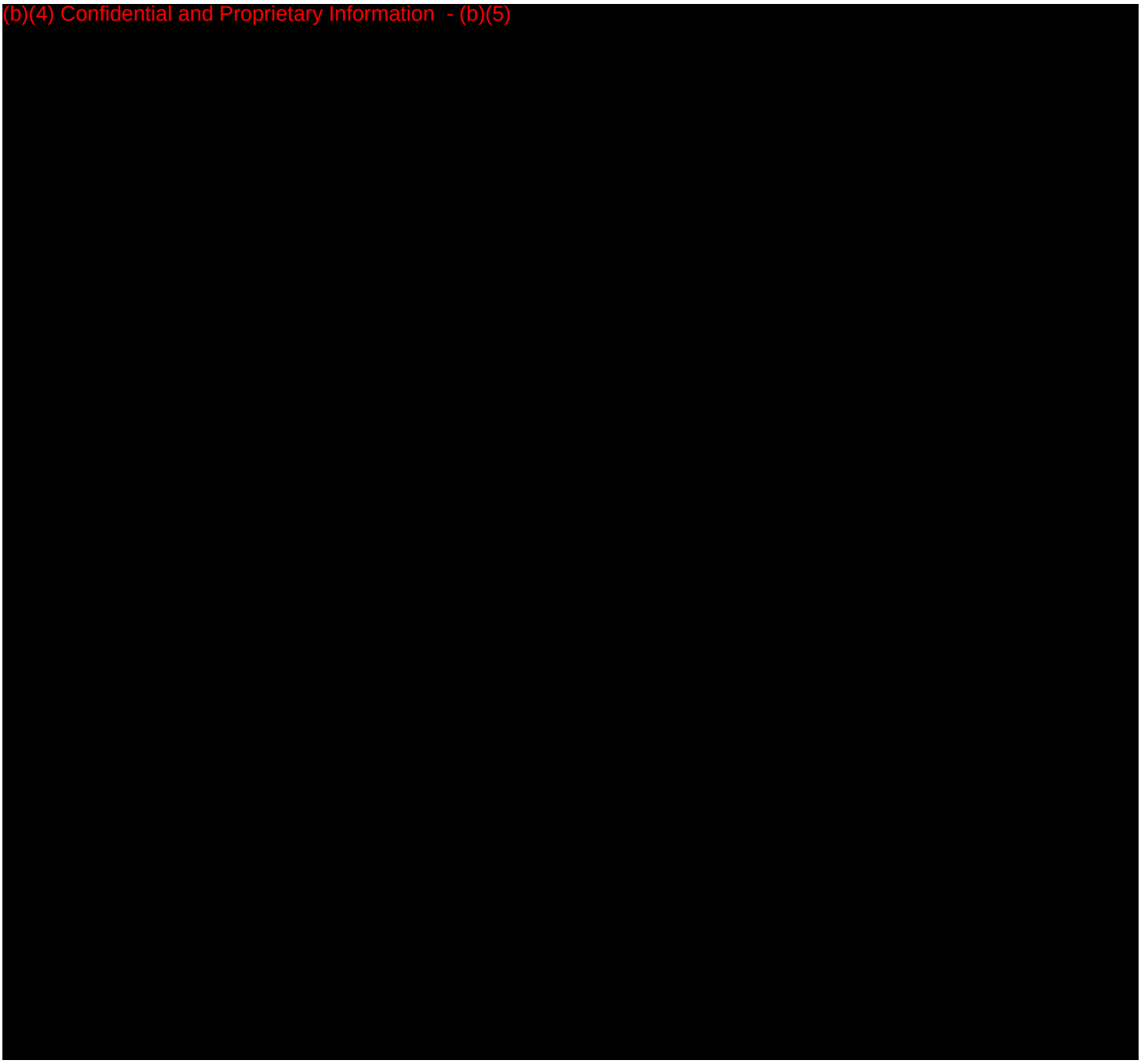



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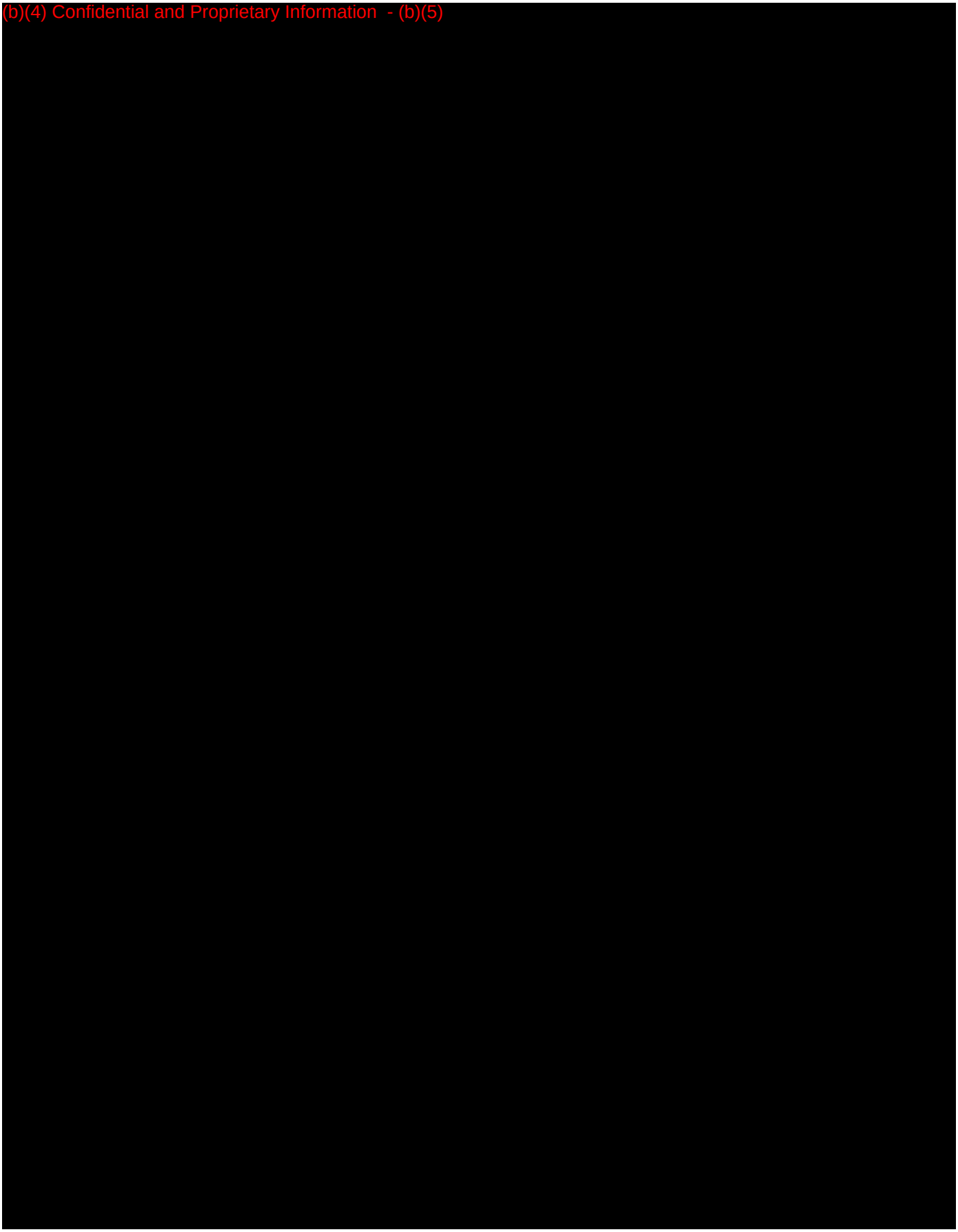



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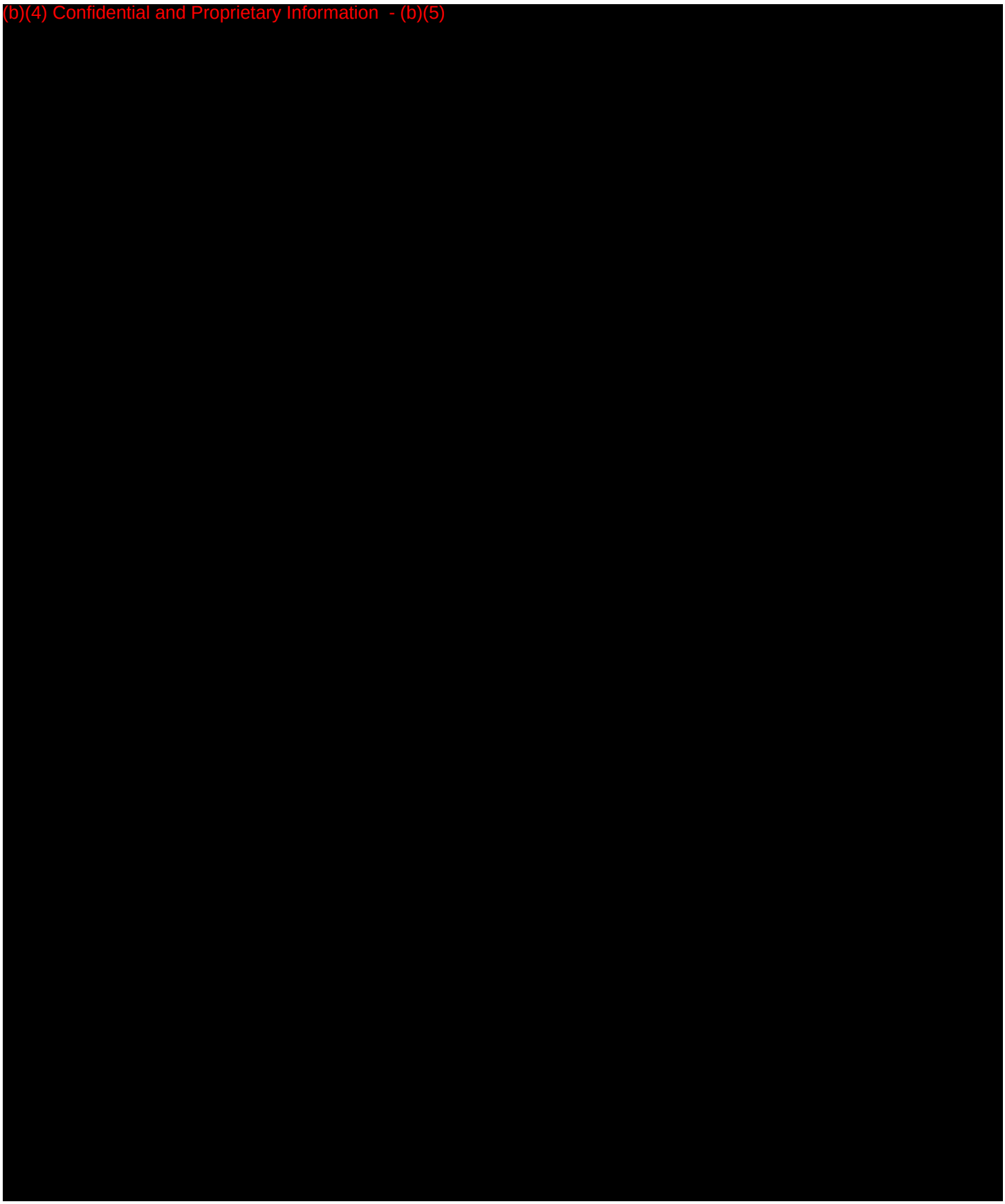



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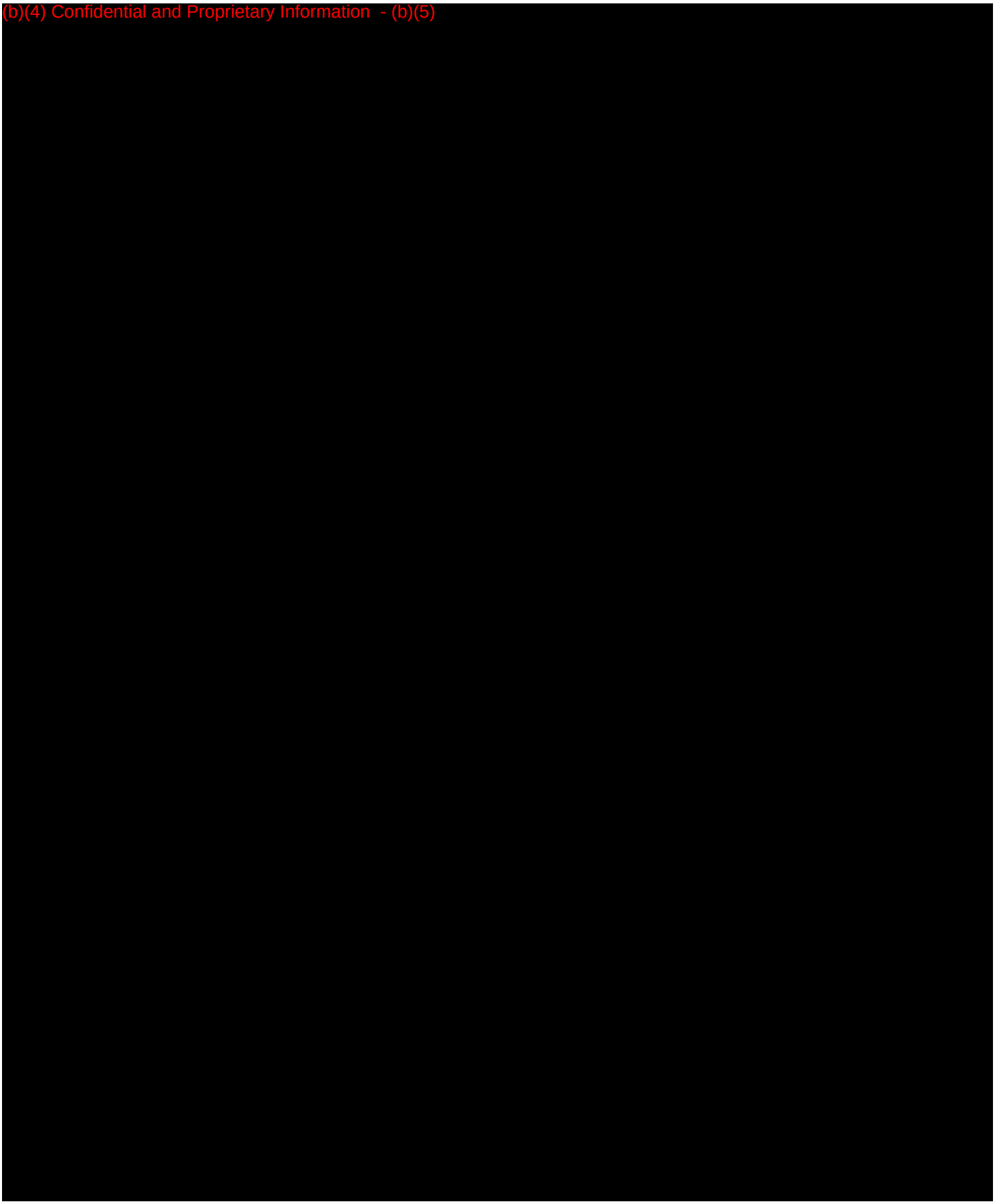



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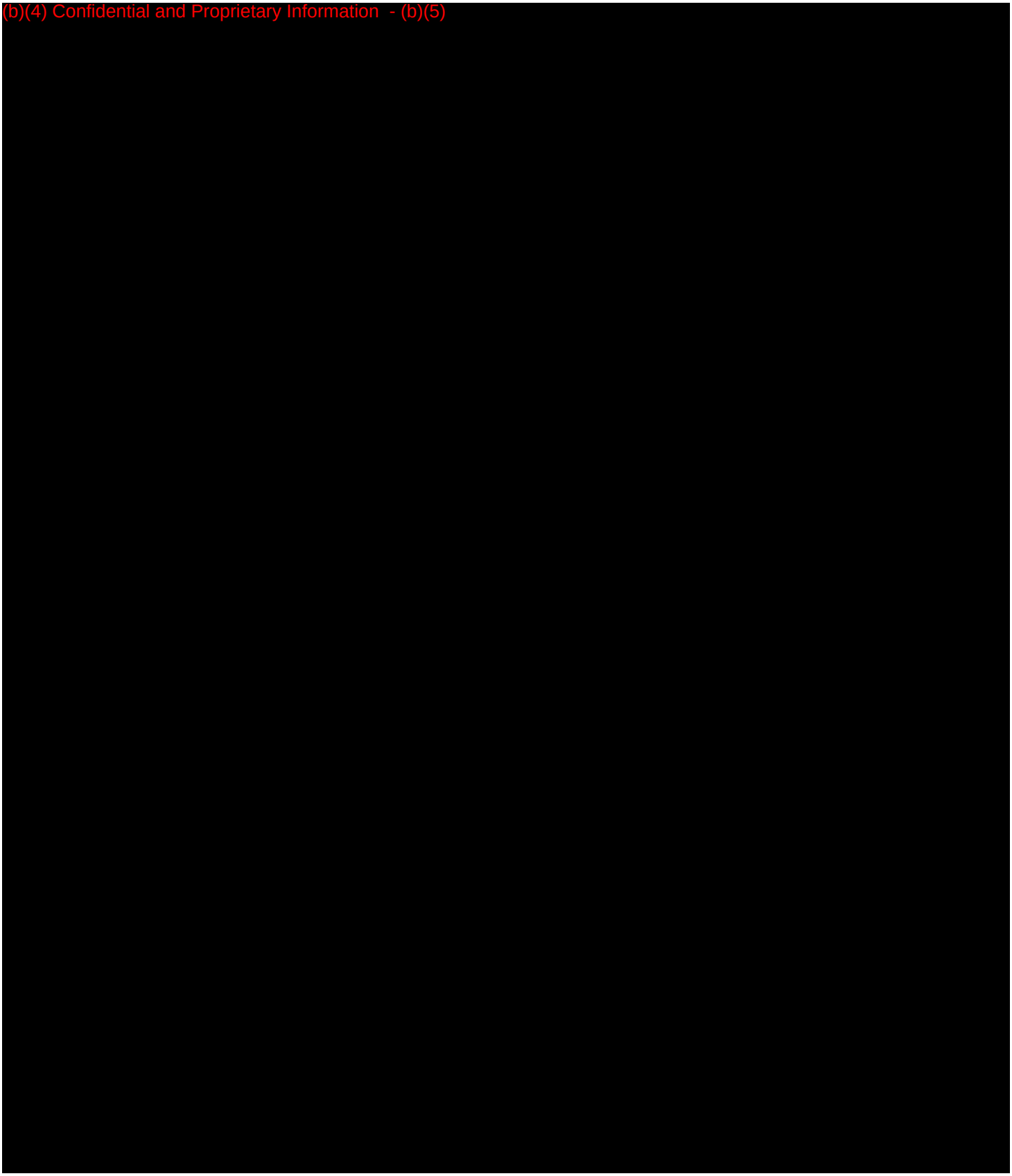



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**XVII. Recommendation: Substantially Equivalent: Benchtop performance testing, sterilization, and biocompatibility are adequate.**
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, DQO

| Digital Signature Concurrence Table | |
|---|---|
| Reviewer Sign-Off | |
| Branch Chief Sign-Off (optional) | |
| Division Sign-Off (optional) | |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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**From:** Hoang, Quynh T.
**To:** Krauthamer, Victor; Whang, Joyce M; Lendor, Marisol
**Cc:** Shimp, Samuel
**Subject:** Due today, K131482 Special RTA1. Thanks.
**Date:** Friday, June 07, 2013 3:28:18 PM

---

Dear Victor and Joyce:

During the call to inform the sponsor of the conversion from Special to Traditional because of they submitted test results and identified 2 new tests, the sponsor offered to withdraw both the data and tests. Since we have allowed other companies to send an email withdrawal, we agreed to this as well.

Pls concur to the RTA1 Special (**file #03**)
https://docs.fda.gov/share/page/site/submissions/documentlibrary#filter=path%7C%2FReviews%2F510%2528k%2529s%2F2013%2F1401%2520-%25201600%2FK131482%2FReviewer%2520Documents%7C&page=1

CTS log out
http://webapps.cdrh.fda.gov/division-tracking/findTrackable.do?docNum=K131482

Thanks.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**From:** Hoang, Quynh T.
**To:** Krauthamer, Victor; Whang, Joyce M
**Cc:** Shimp, Samuel
**Subject:** For division concurrence (pls reply to all), K131482/S1 convert fr Special to Traditional. Thanks.
**Date:** Tuesday, July 02, 2013 11:16:46 PM

---

Dear Victor and Joyce:

In this S1 round, we RTAA file. However, upon an in depth review, we determined that file needs to be converted.

Explanations for the conversion are in document **#05** , available in DocMan at https://docs.fda.gov/share/page/site/submissions/documentlibrary#filter=path%7C%2FReviews%2F510%2528k%2529s%2F2013%2F1401%2520-%25201600%2FK131482%2FReviewer%2520Documents%7C&page=1

Pls reply to all so we know to forward form to 510(k) staff after your concurrence.

Thanks.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 22, 2013

Micro Vention, Inc.
c/o Ms. Naomi Gong
Sr. Regulatory Affairs Project Manager
1311 Valencia Avenue
Tustin, CA 92780

Re: K131482
Trade/Device Name: SOFIA Distal Access Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, DQO
Dated: October 22, 2013
Received: October 23, 2013

Dear Ms. Gong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.


**Concurrence & Template History Page**
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K131482/S002

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

| Digital Signature Concurrence Table | |
|---|---|
| Reviewer Sign-Off | Samuel K. Shimp III<br>11/13/2013 @ 3:08PM |
| Branch Chief Sign-Off | Quynh Hoang<br>November 21, 2013<br>DNPMD/NNDB |
| Division Sign-Off | |

Template Name: K1(A) – SE after 1996

Template History:

| Date of Update | By | Description of Update |
|---|---|---|
| 7/27/09 | Brandi Stuart | Added Updates to Boiler Table |
| 8/7/09 | Brandi Stuart | Updated HFZ Table |
| 1/11/10 | Diane Garcia | Liability/Warranty sentence added at bottom of 1st page |
| 10/4/11 | M. McCabe Janicki | Removed IFU sheet and placed in Forms |
| 9/25/12 | Edwena Jones | Added digital signature format |
| 12/12/12 | M. McCabe Janicki | Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002". |
| 4/2/2013 | M. McCabe Janicki | Edited sentence that starts "If you desire specific advice for your device on our labeling regulation (21 CFR Part 801)…" Replaced broken Compliance link with general link to DSMICA. |
| 4/12/2013 | Margaret McCabe Janicki | Fixed a typo: Paragraph 1, final sentence, "We remind you, however; that device labeling must be truthful…" Replaced incorrect semicolon with a comma. |

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

| 510(k) Summary | |
|---|---|
| **Trade Name:** | SOFIA™ Distal Access Catheter |
| **Generic Name:** | Percutaneous Catheter |
| **Classification:** | Class II, 21 CFR 870.1250 (DQY), 21 CFR 870.1200 (DQO) |
| **Submitted By:** | MicroVention, Inc<br>1311 Valencia Avenue<br>Tustin, California U.S.A. |
| **Contact:** | Naomi Gong |
| **Date:** | 2013 November 13 |
| **Predicate Device:** | Chaperon Guiding Catheter (K082385)<br>Headway Duo Microcatheter (K120917) |

## Device Description:

The SOFIA Distal Access Catheter is a single-lumen, flexible catheter designed with coil and braid reinforcement. The distal segment is steam-shapeable and it has a hydrophilic coating for navigation through the vasculature. The radiopaque marker is located at the distal end of the catheter for visualization under fluoroscopy. An introducer sheath and shaping mandrel are also provided.

## Indications For Use:

The SOFIA Distal Access Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate introduction of diagnostic or therapeutic devices. It is not intended for use in coronary arteries.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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## Technological Comparison:

| | Chaperon Guiding Catheter | SOFIA Distal Access Catheter | Headway Duo Microcatheter |
|---|---|---|---|
| Intended Use | Intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries. | Intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries. | Intended for general intravascular use, including the peripheral and coronary vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as embolization materials. Intended for neurovascular use for the infusion of diagnostic agents, such as contrast media, and therapeutic agents that have been cleared or approved for use in the neurovasculature and are compatible with the inner diameter of the microcatheter. |
| Material | | | |
| Catheter Body | Outer layer of polyester elastomer; stainless steel braid; inner layer of PTFE (polytetrafluoroehthylene). | Outer layer of polyurethane elastomer (Polyblend and Pellethane), polyether block amide (Pebax) and polyamide (Grilamid); inner layer of stainless steel braid/coil, PTFE and polyolefin elastomer | Outer layer of polyether block amide (Pebax) and polyamide (Grilamid); inner layer of stainless steel braid/coil and PTFE |
| Marker | Tungsten | Platinum/Iridium | Platinum/Iridium |
| Hub | Nylon | Nylon | Nylon |
| Strain Relief | Polyester elastomer | Polyurethane | Pebax |
| Introducer | Not applicable | Pebax | Pebax |
| Shaping Mandrel | Not applicable | Stainless steel | Stainless steel |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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| | Chaperon Guiding Catheter | SOFIA Distal Access Catheter | Headway Duo Microcatheter |
|---|---|---|---|
| Catheter size | 5 F (outer catheter) | 5 F | 1.6 - 2.1 F |
| ID | 0.059 inch (1.5 mm) | 0.055 inch (1.4 mm) | 0.0165 inch (0.42 mm) |
| OD | 0.068 inch (1.7 mm) | 0.068 inch (1.7 mm) | 0.023 – 0.0275 inch (0.58 – 0.70 mm) |
| Effective Length | 95 cm (outer)<br>117 cm (inner) | 125 cm | 157 and 168 cm |
| Coating | Hydrophilic coating (Terumo proprietary coating) | Hydrophilic coating (Hydak® – same) | Hydrophilic coating (Hydak® – same) |
| Tip Configuration | Preshaped | Steam shapeable by user | Steam shapeable by user |
| Guidewire Compatibility | 0.035 inch or 0.038 inch | 0.035 inch or 0.038 inch | 0.014 inch or smaller |
| Accessories | N/A | Introducer sheath and shaping mandrel | Introducer sheath and shaping mandrel |
| Method of Supply | Sterile and single use | Sterile and single use | Sterile and single use |
| Sterilization Method | Ethylene Oxide | Ethylene Oxide | Ethylene Oxide |
| Packaging Configuration | Catheter placed on packaging card that is inserted into Tyvek® pouch. Pouch and IFU placed in bleached sulfate carton box. | Catheter placed into a HDPE dispenser tube. Dispenser tube, introducer and shaping mandrel placed on a polyethylene packaging card that is inserted into a Tyvek® pouch. Pouch and IFU placed in bleached sulfate carton box. | Catheter placed into a polyethylene dispenser hoop. Introducer and shaping mandrel placed on polyethylene packaging card. Dispenser hoop and packaging card inserted into Tyvek® pouch. Pouch and IFU placed in bleached sulfate carton box. |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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## Verification and Test Summary:

| **Bench Testing** | | |
|---|---|---|
| **Test** | **Results** | **Conclusions** |
| Simulated Use | Test articles achieved a rating $\geq 3$ for preparation/ease of assembly, introducer sheath interaction, introducer peel away, tracking with guidewire/microcatheter, microcatheter/guidewire lockup, lubricity and durability of hydrophilic coating, microcatheter/ guidewire removal, removal/ aspiration of clot, mechanical clot retriever and stent delivery with no particles | Device performs as intended under simulated use conditions |
| Equipment Interface | Test articles compatible with 0.035-inch and 0.038-inch guidewires, 6F or larger guide catheter/guiding sheath, common RHVs using insertion tool, stopcocks and $\leq$ 0.027-inch microcatheters | Device compatible with recommended accessories commonly used in intravascular procedures |
| Dimensional and Physical Attributes | Test articles met the specified dimensional requirements for catheter OD, catheter ID, overall working length, length of distal section, length of distal tip to marker band and total length of hub/strain relief | Device met established dimensional and physical specifications |
| Kink Resistance | No kinks at 1 cm, 4 cm, 12 cm and 25 cm from distal tip when wrapped around 0.025-inch and 0.030-inch pin gauges<br><br>No kinks noted during simulated use testing | Device resistant to kinking around small radii turns |
| Tip Shapeability | Tip angle of test article equivalent to competitive devices after steam shaping using mandrel with an angle of approximately $90^{o}$ | Shapeability of distal tip after steam shaping equivalent to competitive devices |
| Radio Detectability | Distal marker band visible under fluoroscopy | Device radiopacity equivalent to or better than predicate and competitive devices |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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| **Bench Testing** | | |
|---|---|---|
| **Test** | **Results** | **Conclusions** |
| Gauging (ISO 594-2) | Gauging pin and hub align in limit planes | Device hub meets the requirements of ISO 594-2 |
| Separation Force (ISO 594-2) | Mating parts separation force greater than 25 N | Device hub meets the requirements of ISO 594-2 |
| Unscrewing Torque (ISO 594-2) | Test article luer remains attached after applying an unscrewing torque not less than 0.02 Nm for a minimum of 10 seconds | Device hub meets the requirements of ISO 594-2 |
| Stress Cracking (ISO 594-2) | No stress cracks on test article hub | Device hub meets the requirements of ISO 594-2 |
| Ease of Assembly (ISO 594-2) | Components fit together securely with no resistance observed between test article luer and reference fitting | Device hub meets the requirements of ISO 594-2 |
| Resistance to Overriding (ISO 594-2) | Test article luer does not override reference fitting threads | Device hub meets the requirements of ISO 594-2 |
| Durability/Lubricity of Hydrophilic Coating | Test article achieved a rating of $\geq 3$ during simulated use testing for coating durability and lubricity. | Device tracks easily with no coating cracking or separation |
| Catheter Stiffness | Device stiffness equivalent to predicate and competitive devices | Device tracks in tortuous anatomy while advancing to target site |
| Torque Strength | No catheter breakage after 50 rotations | Device torque strength same as predicate device |
| Catheter Flexural Fatigue | No flexural fatigue following repeated bending during simulated use testing and repeated hoop stress following pressure and air aspiration testing | Device integrity suitable for intended clinical use |
| Surface Contamination | Test article free from surface contaminants from uncured coating surface particulates > 0.02 $mm^2$, embedded particulates<br><br>Distal tip smooth and tapered<br><br>PTFE inner layer not delaminated | Device integrity suitable for intended clinical use |
| Force at Break (Distal and Hub) | Catheter force at break $\geq$2.25lbf for distal section and hub/catheter junction | Tensile strength test results equivalent to predicate and competitive devices |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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| **Bench Testing** | | |
|---|---|---|
| **Test** | **Results** | **Conclusions** |
| Flow Rate | Flow rate at 100 psi and 300 psi with diagnostic agents (e.g., saline, contrast media) equivalent to or better than competitive devices | Device meets specified requirements for delivery of diagnostic agents |
| Static Burst Pressure | No damage of pressurized catheter at 46 psi | Device integrity suitable for intended clinical use and met requirements of ISO 10555-1 |
| Fluid Leakage at > 46 psi | No liquid leakage from hub and catheter shaft at 46 psi for 30 seconds | Device integrity suitable for intended clinical use and met requirements of ISO 10555-1 |
| Air Leakage | No air leakage at hub into syringe for 15 seconds | Device integrity suitable for intended clinical use and met requirements of ISO 10555-1 |
| Dynamic Burst | Test articles did not burst at or below 300 psi | Device met labeled maximum infusion pressure of 300 psi |
| Particulate Test | Less than 25 particles greater than 10 microns per ml volume and less than 3 particles less than 25 microns per ml volume<br><br>No particles greater than 70 microns | Device met specifications for maximum allowable particles |

| **Biocompatibility** | | |
|---|---|---|
| **Test** | **Results** | **Conclusions** |
| Cytotoxicity – MEM Elution Assay (ISO 10993-5) | Cell culture treated with test article exhibited slight reactivity (Grade 1) | Non-cytotoxic |
| Sensitization/Irritation – Kligman Maximization Test (ISO 10993-10) | Extracts of the test article elicited no reaction at the challenge (0% sensitization) following the induction phase (Grade 1). | Weak allergic potential or sensitizing capacity |
| Sensitization/Irritation – Intracutaneous Injection Test (ISO 10993-10) | Extracts of the test article did not show a significantly greater biological reaction than the sites injected with the control article | Non-irritant |
| Hemocompatibility – Rabbit Blood Direct and Indirect Contact (ISO 10993-4) | The hemolysis index was 0.13% (direct contact) and 0.0% (indirect contact) | Non-hemolytic |



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| **Biocompatibility** | | |
|---|---|---|
| **Test** | **Results** | **Conclusions** |
| Hemocompatibility – Unactivated Partial Thromboplastin Time Assay Direct Contact (ISO 10993-4) | No statistically significant difference found between the Unactivated Partial Thromboplastin Time (UPTT) of the plasma exposed to the test article and that of the plasma exposed to either the negative control or the untreated control | No effect on coagulation |
| Hemocompatibility – Complement Activation Assay (ISO 10993-4) | C3a and SC5b-9 levels $\leq$ negative and untreated controls | No effect on complement activation |
| Hemocompatibility – Thrombogenicity Study in Dogs (ISO 10993-4) | Minimal thrombosis observed with a Grade 0 in two out of two test sites and two out of two control sites | No significant thrombosis |
| Systemic Toxicity – Systemic Injection Test (ISO 10993-11) | Extracts of test article did not induce a significantly greater biological reaction than the control extracts when injected in Swiss Albino mice | No toxic effects |
| Systemic Toxicity - Rabbit Pyrogen Test (ISO 10993-11) | The temperature increases (maximum) was 0.03$^{o}$C from baseline | Non-pyrogenic |

## Summary of Substantial Equivalence:

The data presented in this submission demonstrates the technological similarity and equivalency of the SOFIA Distal Access Catheter when compared with the predicate Chaperon Guiding Catheter (K082385) and the HEADWAY DUO Microcatheter (K120917) devices. The devices:

- Have an equivalent intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Are packaged and sterilized using the same methods.

In summary, the SOFIA Distal Access Catheter described in this submission is substantially equivalent to the predicate devices.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

# Indications for Use

510(k) Number (if known): K131482

Device Name: SOFIA Distal Access Catheter

Indications For Use:

*The SOFIA Distal Access Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries.*

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of Center for Devices and Radiological Health (CDRH)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**From:** Hoang, Quynh T.
**To:** Tang, Xiaorui
**Cc:** Shimp, Samuel
**Subject:** Pls forward to Samuel the text you used in your email. Thanks.
**Date:** Tuesday, June 04, 2013 2:02:52 PM

---

Dear Xiaorui:

I remember that in a couple of cases, you contacted the sponsor of a Special 510(k) to tell them that they shouldn't have included the test data in their Special submission and should send an email back to withdraw them from consideration. Please forward that email to Samuel so he has a sample for his case.

Thanks!

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**From:** Hoang, Quynh T.
**To:** Shimp, Samuel
**Subject:** Pls inform the sponsor (w/ another FDA staff present, pls): K131482 Conversion fr Special to Traditional. Thanks.
**Date:** Thursday, June 06, 2013 12:00:06 PM

---

**From:** 510K Program
**Sent:** Thursday, June 06, 2013 7:06 AM
**To:** Hoang, Quynh T.; 510K Program
**Cc:** Shimp, Samuel; Krauthamer, Victor
**Subject:** RE: (Due 6/7) K131482 Conversion fr Special to Traditional. Thanks.

Good Day,

I concur with this conversion because the company provided raw data unsolicited. I have converted K131482 from Special to Traditional. The new (90th day) due date is August 21, 2013. I cannot e-sign the new conversion form, so please include this e-mail in the record as documentation of POS concurrence. Please let the company know about this conversion.

I have also put in a CTS ticket for you, CTSP-15062, to have the dates re-set to align w/Traditional timeframes.

Please let me know if you need anything further.

Margaret

---

**From:** Hoang, Quynh T.
**Sent:** Wednesday, June 05, 2013 5:20 PM
**To:** 510K Program
**Cc:** Shimp, Samuel
**Subject:** (Due 6/7) K131482 Conversion fr Special to Traditional. Thanks.

Dear 510(k) staff:

For your concurrence is the conversion from a Special to a Traditional.

The conversion form is **file #1**, at
https://docs.fda.gov/share/page/site/submissions/documentlibrary#filter=path%7C%2FReviews%2F510%2528k%2529s%2F2013%2F1401%2520-%25201600%2FK131482%2FReviewer%2520Documents%7C&page=1

Once you are done, we'll inform the sponsor of the conversion and log out the RTAA (for a Traditional).

Thanks.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**From:** Hoang, Quynh T.
**To:** Krauthamer, Victor; Whang, Joyce M
**Cc:** Shimp, Samuel
**Subject:** Pls reply to all, (due 6/7) K131482 Conversion fr Special to Traditional. Thanks.
**Date:** Tuesday, June 04, 2013 5:01:17 PM

---

Dear Victor and Joyce:

Pls reply to all, so we know to forward to 510(k) staff for their concurrence of the conversion from a Special to a Traditional.

The conversion form is **file #1**, at https://docs.fda.gov/share/page/site/submissions/documentlibrary#filter=path%7C%2FReviews%2F510%2528k%2529s%2F2013%2F1401%2520-%25201600%2FK131482%2FReviewer%2520Documents%7C&page=1

[Your signature is not required for **file #2** as it's a RTAA. I will then log file out of CTS w/ an RTAA.]

Thanks.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**From:** 510K Program
**To:** Hoang, Quynh T.; 510K Program
**Cc:** Shimp, Samuel; Krauthamer, Victor
**Subject:** RE: (Due 6/7) K131482 Conversion fr Special to Traditional. Thanks.
**Date:** Thursday, June 06, 2013 7:05:34 AM

---

Good Day,

I concur with this conversion because the company provided raw data unsolicited. I have converted K131482 from Special to Traditional. The new (90th day) due date is August 21, 2013. I cannot e-sign the new conversion form, so please include this e-mail in the record as documentation of POS concurrence. Please let the company know about this conversion.

I have also put in a CTS ticket for you, CTSP-15062, to have the dates re-set to align w/Traditional timeframes.

Please let me know if you need anything further.

Margaret

---

**From:** Hoang, Quynh T.
**Sent:** Wednesday, June 05, 2013 5:20 PM
**To:** 510K Program
**Cc:** Shimp, Samuel
**Subject:** (Due 6/7) K131482 Conversion fr Special to Traditional. Thanks.

Dear 510(k) staff:

For your concurrence is the conversion from a Special to a Traditional.

The conversion form is **file #1**, at
https://docs.fda.gov/share/page/site/submissions/documentlibrary#filter=path%7C%2FReviews%2F510%2528k%2529s%2F2013%2F1401%2520-%25201600%2FK131482%2FReviewer%2520Documents%7C&page=1

Once you are done, we'll inform the sponsor of the conversion and log out the RTAA (for a Traditional).

Thanks.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**From:** Chao, Kuo
**To:** Shimp, Samuel
**Subject:** RE: Another Tortuous Model - pls comment
**Date:** Tuesday, November 12, 2013 11:03:31 PM

It looks reasonable to me.

**From:** Shimp, Samuel
**Sent:** Tuesday, November 12, 2013 2:50 PM
**To:** Misra, Sanjay; Chao, Kuo; Froehler, Michael
**Cc:** Toy, Jeffrey; Zheng, Xiaolin
**Subject:** Another Tortuous Model - pls comment

(b) (5)

[redacted]

- Samuel

Samuel K. Shimp III, Ph.D.
Mechanical/Biomedical Engineer
FDA/CDRH/ODE/DNPMD/NNDB
WO66, Rm 1430

(301) 796-6610
Samuel.Shimp@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**From:** Toy, Jeffrey
**To:** Shimp, Samuel
**Subject:** RE: Are these adequate tests?
**Date:** Thursday, June 27, 2013 3:33:59 PM

There are no other tests.

Yes, you can. In the future, I'm going to adjust the deficiency to outline the type of info I expect if a sponsor should wishes to omit genotox testing.

Jeffrey Toy, Ph.D.

---

**From:** Shimp, Samuel
**Sent:** Thursday, June 27, 2013 3:28 PM
**To:** Toy, Jeffrey
**Subject:** RE: Are these adequate tests?

Any other tests that we would require besides genotox? Can I regurgitate your genotox deficiency from Reverse Medical?

- Samuel

---

**From:** Toy, Jeffrey
**Sent:** Thursday, June 27, 2013 3:27 PM
**To:** Shimp, Samuel
**Subject:** RE: Are these adequate tests?

Samuel,

The sponsor has not addressed genotoxicity risk. If the sponsor wishes to omit genotoxicity testing the justification should be based on data and not hand waiving or a statement like the device material has a long history of use. Sponsors should know the chemicals that went into the manufacture of the device and demonstrate the residuals that leach out is consistent with what they put in (no unexplained new peaks on a chromatogram).

Jeffrey Toy, Ph.D.

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**From:** Shimp, Samuel
**Sent:** Thursday, June 27, 2013 2:52 PM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**To:** Toy, Jeffrey
**Subject:** Are these adequate tests?

Hi Jeff:

For a catheter with a near-complete change of materials, would these biocompatibility tests be adequate? It does not look to me like they did genotox. Are there other tests that they would need to do?

- Samuel

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**From:** Toy, Jeffrey
**To:** Shimp, Samuel
**Subject:** RE: Are these adequate tests?
**Date:** Thursday, June 27, 2013 3:27:14 PM

Samuel,

The sponsor has not addressed genotoxicity risk. If the sponsor wishes to omit genotoxicity testing the justification should be based on data and not hand waiving or a statement like the device material has a long history of use. Sponsors should know the chemicals that went into the manufacture of the device and demonstrate the residuals that leach out is consistent with what they put in (no unexplained new peaks on a chromatogram).

Jeffrey Toy, Ph.D.

---

**From:** Shimp, Samuel
**Sent:** Thursday, June 27, 2013 2:52 PM
**To:** Toy, Jeffrey
**Subject:** Are these adequate tests?

Hi Jeff:

For a catheter with a near-complete change of materials, would these biocompatibility tests be adequate? It does not look to me like they did genotox. Are there other tests that they would need to do?

- Samuel

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**From:** Ghosh, Molly
**To:** Shimp, Samuel
**Subject:** RE: Cancelled Consult for K131482
**Date:** Friday, June 07, 2013 3:05:59 PM

Ok. Thx.

**From:** Shimp, Samuel
**Sent:** Friday, June 07, 2013 3:05 PM
**To:** Ghosh, Molly
**Subject:** Cancelled Consult for K131482

Hi Molly,
I had to cancel the consult for the file because the sponsor insisted that they wanted the file to remain as a special 510(k) and not be converted. Once I did the special 510(k) review we found that it needed to be RTA1. So, there is no need for the consult until they fix their submission and resubmit. I'll let you know if I need you, otherwise, Jeff might end up doing it at that time.

- Samuel

Samuel K. Shimp III, Ph.D.
Biomedical Engineer
FDA/CDRH/ODE/DNPMD/NNDB
WO66, Rm 2250

(301) 796-6610
Samuel.Shimp@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**From:** Whang, Joyce M
**To:** Lendor, Marisol
**Cc:** Shimp, Samuel; Hoang, Quynh T.; Krauthamer, Victor
**Subject:** RE: Due today, K131482 Special RTA1. Thanks.
**Date:** Friday, June 07, 2013 3:48:27 PM

Concurred.

Marisol: Please return this document to DCC with the RTA1 coversheet. Thanks.

**From:** Hoang, Quynh T.
**Sent:** Friday, June 07, 2013 3:28 PM
**To:** Krauthamer, Victor; Whang, Joyce M; Lendor, Marisol
**Cc:** Shimp, Samuel
**Subject:** Due today, K131482 Special RTA1. Thanks.

Dear Victor and Joyce:

During the call to inform the sponsor of the conversion from Special to Traditional because of they submitted test results and identified 2 new tests, the sponsor offered to withdraw both the data and tests. Since we have allowed other companies to send an email withdrawal, we agreed to this as well.

PIs concur to the RTA1 Special (**file #03**)
https://docs.fda.gov/share/page/site/submissions/documentlibrary#filter=path%7C%2FReviews%2F510%2528k%2529s%2F2013%2F1401%2520-%25201600%2FK131482%2FReviewer%2520Documents%7C&page=1

CTS log out
http://webapps.cdrh.fda.gov/division-tracking/findTrackable.do?docNum=K131482

Thanks.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**From:** Hoang, Quynh T.
**To:** Shimp, Samuel
**Subject:** RE: For division concurrence (pls reply to all), K131482/S1 convert fr Special to Traditional. Thanks.
**Date:** Wednesday, July 03, 2013 9:42:12 AM

Dear Samuel:

If you haven't done so, pls forward to 510(k) staff for their OK before calling.

Pls alert me if you need my involvement; otherwise, I'll assume that it's a done deal.

Thanks.

---

**From:** Shimp, Samuel
**Sent:** Wednesday, July 03, 2013 9:39 AM
**To:** Hoang, Quynh T.
**Subject:** RE: For division concurrence (pls reply to all), K131482/S1 convert fr Special to Traditional. Thanks.

I will give the firm a call today and let them know. I'll get Jeff or Lin to attend the call.

- Samuel

---

**From:** Whang, Joyce M
**Sent:** Wednesday, July 03, 2013 9:31 AM
**To:** Hoang, Quynh T.; Krauthamer, Victor
**Cc:** Shimp, Samuel
**Subject:** RE: For division concurrence (pls reply to all), K131482/S1 convert fr Special to Traditional. Thanks.

I have concurred in DocMan.

---

**From:** Hoang, Quynh T.
**Sent:** Tuesday, July 02, 2013 11:17 PM
**To:** Krauthamer, Victor; Whang, Joyce M
**Cc:** Shimp, Samuel
**Subject:** For division concurrence (pls reply to all), K131482/S1 convert fr Special to Traditional. Thanks.

Dear Victor and Joyce:

In this S1 round, we RTAA file. However, upon an in depth review, we determined that file needs to be converted.

Explanations for the conversion are in document **#05** , available in DocMan at https://docs.fda.gov/share/page/site/submissions/documentlibrary#filter=path%7C%2FReviews%2F510%2528k%2529s%2F2013%2F1401%2520-%25201600%2FK131482%2FReviewer%2520Documents%7C&page=1

Pls reply to all so we know to forward form to 510(k) staff after your concurrence.

Thanks.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**From:** Lee, Patty
**To:** 510K Program; Shimp, Samuel
**Cc:** Hoang, Quynh T.
**Subject:** RE: For your concurrence, K131482/S1 convert fr Special to Traditional. Thanks.
**Date:** Wednesday, July 03, 2013 10:34:57 AM

Geeta,

converted

*Patty Lee*
OIM/DSM/CDRH IP Team
301-796-7783 (Office)
240-506-7039 (BB)

**From:** 510K Program
**Sent:** Wednesday, July 03, 2013 9:58 AM
**To:** Shimp, Samuel; 510K Program; Lee, Patty
**Cc:** Hoang, Quynh T.
**Subject:** RE: For your concurrence, K131482/S1 convert fr Special to Traditional. Thanks.

Hi Patty,

510k staff concurs with the request to convert this special to traditional. This file is on S1 and I am unable to convert in APPS. Will you please complete this conversion when you get a chance?

Thank you,
Geeta

**From:** Shimp, Samuel
**Sent:** Wednesday, July 03, 2013 9:45 AM
**To:** 510K Program
**Cc:** Hoang, Quynh T.
**Subject:** FW: For your concurrence, K131482/S1 convert fr Special to Traditional. Thanks.

Please follow the link below. Please call or email if you have any questions.

- Samuel

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**To:** Lee, Patty; 510K Program; Shimp, Samuel
**Cc:** Hoang, Quynh T.
**Subject:** RE: For your concurrence, K131482/S1 convert fr Special to Traditional. Thanks.
**Date:** Wednesday, July 03, 2013 10:36:35 AM

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As always, many thanks for your quick action, Patty. Have a good 4th

---

**From:** Lee, Patty
**Sent:** Wednesday, July 03, 2013 10:35 AM
**To:** 510K Program; Shimp, Samuel
**Cc:** Hoang, Quynh T.
**Subject:** RE: For your concurrence, K131482/S1 convert fr Special to Traditional. Thanks.

Geeta,

converted

*Patty Lee*
OIM/DSM/CDRH IP Team
301-796-7783 (Office)
240-506-7039 (BB)

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**Cc:** Hoang, Quynh T.
**Subject:** RE: For your concurrence, K131482/S1 convert fr Special to Traditional. Thanks.

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Thank you,
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Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**From:** Lee, Patty
**To:** Shimp, Samuel
**Cc:** Jasper, Chad B *
**Subject:** RE: For your concurrence, K131482/S1 convert fr Special to Traditional. Thanks.
**Date:** Monday, July 08, 2013 9:57:54 AM

Samuel – I'm only handle APPS data. In APPS, K131482 has been converted to traditional last Friday (7/3). S001 was received on 6/12/2013 and it I is due on 09/10/2013.

Chad – Please check CTS, see Samuel Shimp's email below, thanks.

*Patty Lee*

OIM/DSM/CDRH IP Team
301-796-7783 (Office)
240-506-7039 (BB)

---

**From:** Shimp, Samuel
**Sent:** Monday, July 08, 2013 9:46 AM
**To:** Lee, Patty
**Subject:** RE: For your concurrence, K131482/S1 convert fr Special to Traditional. Thanks.

Hi Patty,

K131482/S001 still shows up as a special (i.e. the deadlines have not changed in CTS). Can you please look into this and see that the deadlines are updated to reflect that it is a traditional?

- Samuel

---

**From:** Lee, Patty
**Sent:** Wednesday, July 03, 2013 10:35 AM
**To:** 510K Program; Shimp, Samuel
**Cc:** Hoang, Quynh T.
**Subject:** RE: For your concurrence, K131482/S1 convert fr Special to Traditional. Thanks.

Geeta,

converted

*Patty Lee*

OIM/DSM/CDRH IP Team
301-796-7783 (Office)
240-506-7039 (BB)

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Please follow the link below. Please call or email if you have any questions.

- Samuel

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(b) (5)

[redacted]

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510k staff concurs with the request to convert this special to traditional. This file is on S1 and I am unable to convert in APPS. Will you please complete this conversion when you get a chance?

Thank you,
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Thanks.

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**From:** Hoang, Quynh T.
**To:** Shimp, Samuel
**Subject:** RE: K131482 - Convert Special to Traditional: Unsolicited Data/Full Test Reports
**Date:** Tuesday, June 04, 2013 3:02:37 PM

Dear Samuel:

New tests / performance criteria mean that the existing design controls do not adequately cover the new device. This removes the new device from a Special. Sorry, no email will fix this one.

Pls convert. Thanks.

---

**From:** Shimp, Samuel
**Sent:** Tuesday, June 04, 2013 2:58 PM
**To:** Hoang, Quynh T.
**Subject:** RE: K131482 - Convert Special to Traditional: Unsolicited Data/Full Test Reports

Hi Quynh,

Even though the old device was a 2 catheter system, I talked to Mike Froehler and he felt that the device was the same, no new technology. Same basic usage principles as the predicate. However, there are two new tests being conducted on the new device and one of the repeated tests seems to have new criteria for the current sub. I would be comfortable reviewing it as a special as long as I could ask for clarification (interactively) on test protocol for one or two of the new tests.

- Samuel

---

**From:** Hoang, Quynh T.
**Sent:** Tuesday, June 04, 2013 1:52 PM
**To:** Shimp, Samuel
**Subject:** RE: K131482 - Convert Special to Traditional: Unsolicited Data/Full Test Reports

Dear Samuel:

Is the inclusion of data the only reason for the conversion? If so, we just make a call or send an email to ask the sponsor to respond in an email that they inadvertently submitted the data and request to withdraw those data and that the FDA would ignore them in our review.

Thanks.

---

**From:** Shimp, Samuel
**Sent:** Tuesday, June 04, 2013 8:31 AM
**To:** Hoang, Quynh T.
**Subject:** K131482 - Convert Special to Traditional: Unsolicited Data/Full Test Reports

Hi Quynh,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

The Sofia Distal Access Catheter file (K131482) included full test reports for bench top and biocompatibility testing. The file seems to have considerable changes to materials and possibly design and I think the inclusion of the reports is warranted, however, it required review as a traditional and not a special 510(k). The conversion form is uploaded to DM in the Reviewer Docs. I am now working on the traditional 510(k) RTA. (RTA is due Friday)

- Samuel

Samuel K. Shimp III, Ph.D.
Biomedical Engineer
FDA/CDRH/ODE/DNPMD/NNDB
WO66, Rm 2250

(301) 796-6610
Samuel.Shimp@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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**From:** Hoang, Quynh T.
**To:** Shimp, Samuel
**Subject:** RE: K131482 - Convert Special to Traditional: Unsolicited Data/Full Test Reports
**Date:** Tuesday, June 04, 2013 1:52:22 PM

Dear Samuel:

Is the inclusion of data the only reason for the conversion? If so, we just make a call or send an email to ask the sponsor to respond in an email that they inadvertently submitted the data and request to withdraw those data and that the FDA would ignore them in our review.

Thanks.

**From:** Shimp, Samuel
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Hi Quynh,

The Sofia Distal Access Catheter file (K131482) included full test reports for bench top and biocompatibility testing. The file seems to have considerable changes to materials and possibly design and I think the inclusion of the reports is warranted, however, it required review as a traditional and not a special 510(k). The conversion form is uploaded to DM in the Reviewer Docs. I am now working on the traditional 510(k) RTA. (RTA is due Friday)

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Samuel K. Shimp III, Ph.D.
Biomedical Engineer
FDA/CDRH/ODE/DNPMD/NNDB
WO66, Rm 2250

(301) 796-6610
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**From:** Ghosh, Molly
**To:** Shimp, Samuel
**Cc:** Marjenin, Timothy
**Subject:** RE: K131482 - Sofia Catheter
**Date:** Friday, June 07, 2013 8:42:13 AM

No problem! 7/1 works.

**From:** Shimp, Samuel
**Sent:** Friday, June 07, 2013 7:55 AM
**To:** Ghosh, Molly
**Cc:** Marjenin, Timothy
**Subject:** K131482 - Sofia Catheter

Hi Molly,
(cc: Tim "Consult Gatekeeper" Marjenin )

Since Jeff is away for a few weeks, would you mind taking a look at this catheter for biocompatibility? Just as an FYI, they submitted the file as a special but included full test reports and a couple of new tests that got it converted to a traditional 510(k).

Please let me know if you have any questions or concerns. I set the due date for the consult to 7/1. I'm not sure how busy you are so let me know if you need more time. Thanks!

- Samuel

Samuel K. Shimp III, Ph.D.
Biomedical Engineer
FDA/CDRH/ODE/DNPMD/NNDB
WO66, Rm 2250

(301) 796-6610
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**From:** Lee, Patty
**To:** McCabe-Janicki, Margaret; Shimp, Samuel
**Cc:** Clayton, Jeff
**Subject:** RE: K131482/s001 - Please convert back to Special
**Date:** Friday, June 21, 2013 1:19:58 PM

Margaret – This 510k has been converted to special

*Patty Lee*
OIM/DSM/CDRH IP Team
301-796-7783 (Office)
240-506-7039 (BB)

**From:** McCabe-Janicki, Margaret
**Sent:** Friday, June 21, 2013 12:12 PM
**To:** Shimp, Samuel; Lee, Patty
**Cc:** Clayton, Jeff
**Subject:** RE: K131482/s001 - Please convert back to Special

Hi Samuel – sure. If we convert solely because they provided the raw data, then they do have the option of withdrawing the data and giving us summary data & risk analysis instead. Then we have to convert it back to Special.

Hi Patty or Jeff – I can't do this conversion b/c the file has had a supplement. Can you please convert the subject 510(k) back to Special?

Thx!
Margaret

**From:** Shimp, Samuel
**Sent:** Friday, June 21, 2013 12:08 PM
**To:** McCabe-Janicki, Margaret
**Subject:** K131482/s001 - Special Converted to Traditional but now needs to go back to Special

Margaret:

This is an annoying file. They submitted as special but we determined it should be Traditional because they submitted new tests and complete data. When we called to notify of the conversion they insisted on retracting the data and tests and having it converted back to special. However as a special it did not make the RTA cut so it was RTA'ed. I had thought it was reconverted back to special last time around. Now it is back and will be accepted by RTA (RTAA) but I noticed the file is still listed as a traditional. Bottom line, can you please make the file "special"…for now ☺…

- Samuel

Samuel K. Shimp III, Ph.D.
Biomedical Engineer
FDA/CDRH/ODE/DNPMD/NNDB
WO66, Rm 1430

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**From:** McCabe-Janicki, Margaret
**To:** Lee, Patty; Shimp, Samuel
**Cc:** Clayton, Jeff
**Subject:** RE: K131482/s001 - Please convert back to Special
**Date:** Friday, June 21, 2013 1:21:59 PM

Hi Patty – thank you.

Hi Samuel – I have put in a CTS ticket for you, CTSP-15241, to have the dates set back to Special timelines.

Margaret

---

**From:** Lee, Patty
**Sent:** Friday, June 21, 2013 1:20 PM
**To:** McCabe-Janicki, Margaret; Shimp, Samuel
**Cc:** Clayton, Jeff
**Subject:** RE: K131482/s001 - Please convert back to Special

Margaret – This 510k has been converted to special

*Patty Lee*
OIM/DSM/CDRH IP Team
301-796-7783 (Office)
240-506-7039 (BB)

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**Subject:** RE: K131482/s001 - Please convert back to Special
**Date:** Friday, June 21, 2013 12:11:39 PM

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**Subject:** K131482/s001 - Special Converted to Traditional but now needs to go back to Special

Margaret:

This is an annoying file. They submitted as special but we determined it should be Traditional because they submitted new tests and complete data. When we called to notify of the conversion they insisted on retracting the data and tests and having it converted back to special. However as a special it did not make the RTA cut so it was RTA'ed. I had thought it was reconverted back to special last time around. Now it is back and will be accepted by RTA (RTAA) but I noticed the file is still listed as a traditional. Bottom line, can you please make the file "special"…for now ☺…

- Samuel

Samuel K. Shimp III, Ph.D.
Biomedical Engineer
FDA/CDRH/ODE/DNPMD/NNDB
WO66, Rm 1430

(301) 796-6610
Samuel.Shimp@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**From:** Hoang, Quynh T.
**To:** Shimp, Samuel
**Subject:** RE: K131482/S002 I received file but it is not yet assigned in CTS.
**Date:** Wednesday, October 30, 2013 4:36:03 PM

Thanks, Samuel. I must have forgotten to save on CTS after assigning file to you. It's now fixed.

**From:** Shimp, Samuel
**Sent:** Wednesday, October 30, 2013 3:28 PM
**To:** Hoang, Quynh T.
**Subject:** K131482/S002 I received file but it is not yet assigned in CTS.

Samuel K. Shimp III, Ph.D.
Mechanical/Biomedical Engineer
FDA/CDRH/ODE/DNPMD/NNDB
WO66, Rm 1430

(301) 796-6610
Samuel.Shimp@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**From:** Getzoff, Natalie B
**To:** Shimp, Samuel
**Subject:** RE: K131482-S001 MicroVention Sofia Catheter RTAA
**Date:** Friday, June 21, 2013 1:26:02 PM

So do I just concur?

Natalie Getzoff, MD, Medical Officer
Office of Combination Products *(detail)*
Food and Drug Administration

tel: 301-796-6495
natalie.getzoff@fda.hhs.gov

---

**From:** Shimp, Samuel
**Sent:** Friday, June 21, 2013 12:04 PM
**To:** Getzoff, Natalie B
**Subject:** K131482-S001 MicroVention Sofia Catheter RTAA

They took care of the RTA deficiencies so we can accept this file now. The RTA Checklist is here:
https://docs.fda.gov/share/page/site/submissions/documentlibrary#filter=path%7C%2FReviews%2F510%2528k%2529s%2F2013%2F1401%2520-%25201600%2FK131482%2FReviewer%2520Documents%7C&page=1

Note, the RTA is not due until 6/27 (next Thursday) so you may be able to ignore this and pass it on to Quynh.

- Samuel

Samuel K. Shimp III, Ph.D.
Biomedical Engineer
FDA/CDRH/ODE/DNPMD/NNDB
WO66, Rm 1430

(301) 796-6610
Samuel.Shimp@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**From:** Hoang, Quynh T.
**To:** Shimp, Samuel
**Subject:** RE: Pls inform the sponsor (w/ another FDA staff present, pls): K131482 Conversion fr Special to Traditional. Thanks.
**Date:** Thursday, June 06, 2013 4:13:32 PM

---

Thanks. Samuel. If they are unavailable when you call tomorrow, pls email the conversion form. I'll then follow with the CTS log-out.

---

**From:** Shimp, Samuel
**Sent:** Thursday, June 06, 2013 3:55 PM
**To:** Hoang, Quynh T.
**Subject:** RE: Pls inform the sponsor (w/ another FDA staff present, pls): K131482 Conversion fr Special to Traditional. Thanks.

Lin and I tried to contact the sponsor but they did not answer so I emailed them to arrange a phone call for tomorrow.

- Samuel

---

**From:** Hoang, Quynh T.
**Sent:** Thursday, June 06, 2013 12:00 PM
**To:** Shimp, Samuel
**Subject:** Pls inform the sponsor (w/ another FDA staff present, pls): K131482 Conversion fr Special to Traditional. Thanks.

---

**From:** 510K Program
**Sent:** Thursday, June 06, 2013 7:06 AM
**To:** Hoang, Quynh T.; 510K Program
**Cc:** Shimp, Samuel; Krauthamer, Victor
**Subject:** RE: (Due 6/7) K131482 Conversion fr Special to Traditional. Thanks.

Good Day,

I concur with this conversion because the company provided raw data unsolicited. I have converted K131482 from Special to Traditional. The new (90th day) due date is August 21, 2013. I cannot e-sign the new conversion form, so please include this e-mail in the record as documentation of POS concurrence. Please let the company know about this conversion.

I have also put in a CTS ticket for you, CTSP-15062, to have the dates re-set to align w/Traditional timeframes.

Please let me know if you need anything further.

Margaret

---

**From:** Hoang, Quynh T.
**Sent:** Wednesday, June 05, 2013 5:20 PM
**To:** 510K Program
**Cc:** Shimp, Samuel
**Subject:** (Due 6/7) K131482 Conversion fr Special to Traditional. Thanks.

Dear 510(k) staff:

For your concurrence is the conversion from a Special to a Traditional.

The conversion form is **file #1**, at
https://docs.fda.gov/share/page/site/submissions/documentlibrary#filter=path%7C%2FReviews%2F510%2528k%2529s%2F2013%2F1401%2520-%25201600%2FK131482%2FReviewer%2520Documents%7C&page=1

Once you are done, we'll inform the sponsor of the conversion and log out the RTAA (for a Traditional).

Thanks.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**From:** Krauthamer, Victor
**To:** Hoang, Quynh T.
**Cc:** Shimp, Samuel; Whang, Joyce M
**Subject:** RE: Pls reply to all, (due 6/7) K131482 Conversion fr Special to Traditional. Thanks.
**Date:** Tuesday, June 04, 2013 5:36:39 PM

Quynh,

I signed both forms. Please do the CTS log out.

Victor

---

**From:** Hoang, Quynh T.
**Sent:** Tuesday, June 04, 2013 5:01 PM
**To:** Krauthamer, Victor; Whang, Joyce M
**Cc:** Shimp, Samuel
**Subject:** Pls reply to all, (due 6/7) K131482 Conversion fr Special to Traditional. Thanks.

Dear Victor and Joyce:

Pls reply to all, so we know to forward to 510(k) staff for their concurrence of the conversion from a Special to a Traditional.

The conversion form is **file #1**, at
https://docs.fda.gov/share/page/site/submissions/documentlibrary#filter=path%7C%2FReviews%2F510%2528k%2529s%2F2013%2F1401%2520-%25201600%2FK131482%2FReviewer%2520Documents%7C&page=1

[Your signature is not required for **file #2** as it's a RTAA. I will then log file out of CTS w/ an RTAA.]

Thanks.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**From:** Hoang, Quynh T.
**To:** Shimp, Samuel
**Subject:** RE: To RTA or not to RTA? (K131482)
**Date:** Tuesday, June 04, 2013 11:45:16 AM

Dear Samuel:

Your reasoning is sound. I don't believe Form 3514 is a part of the RTA process. The other item #9 is not RTA1 by itself.

Thanks.

---

**From:** Shimp, Samuel
**Sent:** Tuesday, June 04, 2013 9:15 AM
**To:** Hoang, Quynh T.
**Subject:** To RTA or not to RTA? (K131482)

K131482 needs to be converted from special to traditional (see previous email). However, it looks like it is acceptable (RTAA) for a traditional 510(k) except for 2 things:

- The firm cites standards and used form 3654 to identify the extent to which each standard was conformed to BUT they didn't fill out the section I of the CDRH Premarket Review Submission Cover Sheet (form 3514) in which they are supposed to give the list of standards they conform to. The way I read the deficiency, this is not technically an RTA offense (Traditional RTA checklist #8).
- The firm did not state whether or not there were prior submissions. (RTA checklist #9). My understanding is that this alone is not supposed to warrant an RTA but can be cited if there are other issues. Since this is a modification to an existing catheter I don't really think that there were prior submissions.

How do you suggest I proceed?

(Checklist attached for your reference.)

- Samuel

Samuel K. Shimp III, Ph.D.
Biomedical Engineer
FDA/CDRH/ODE/DNPMD/NNDB
WO66, Rm 2250

(301) 796-6610
Samuel.Shimp@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES** **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation

**K131482/S001**

Date: August 9, 2013

To: MicroVention
% Naomi Gong
Phone: (714) 247-8055
Fax: (714) 247-8014
Email: Naomi.Gong@microvention.com

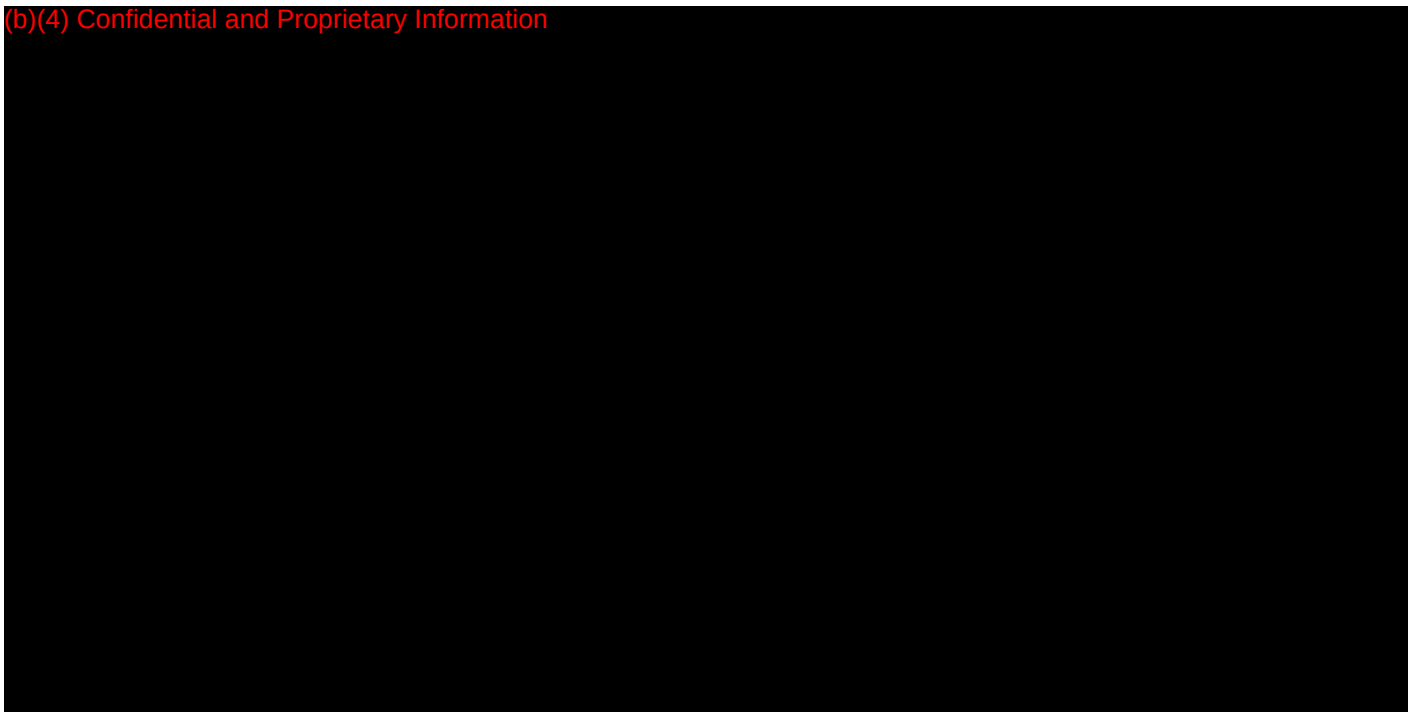
From: Samuel Shimp, Ph.D., Biomedical Engineer

Subject: Telephone hold for K131482/S001 for the SOFIA Distal Access Catheter

Dear Ms. Gong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided; this document serves to notify you that we have placed the file on hold. To complete the review of your submission, we require that you respond to the following deficiencies:

(b)(4) Confidential and Proprietary Information




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information

[redacted]


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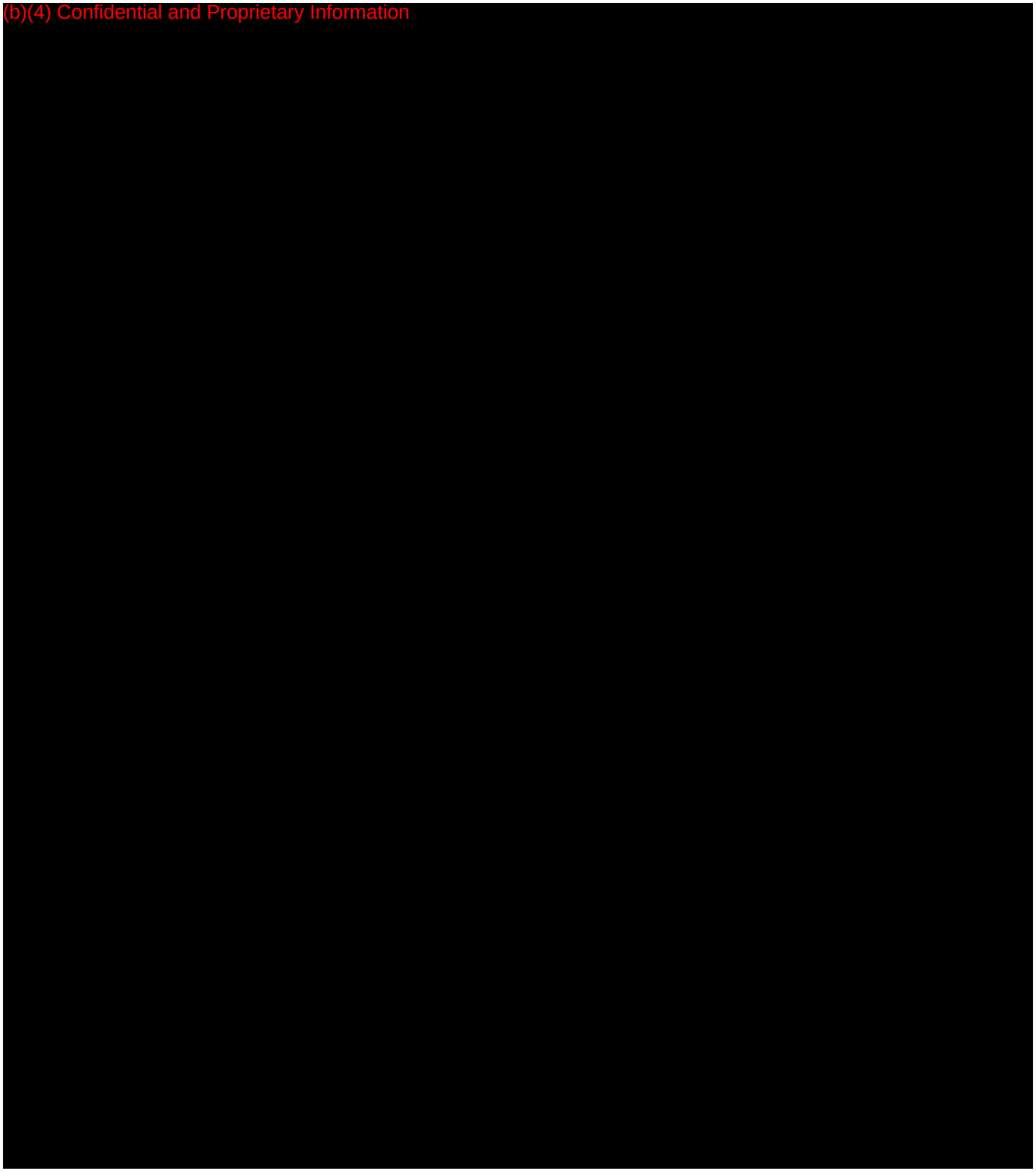


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Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

(b)(4) Confidential and Proprietary Information

[redacted]

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 180 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 180 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm.

The requested information should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact me by email at Samuel.Shimp@fda.hhs.gov or by phone at (301) 796-6610. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.


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**DEPARTMENT OF HEALTH AND HUMAN SERVICES** **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation

**K131482/S001**

Date: August 9, 2013

To: MicroVention
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[redacted]


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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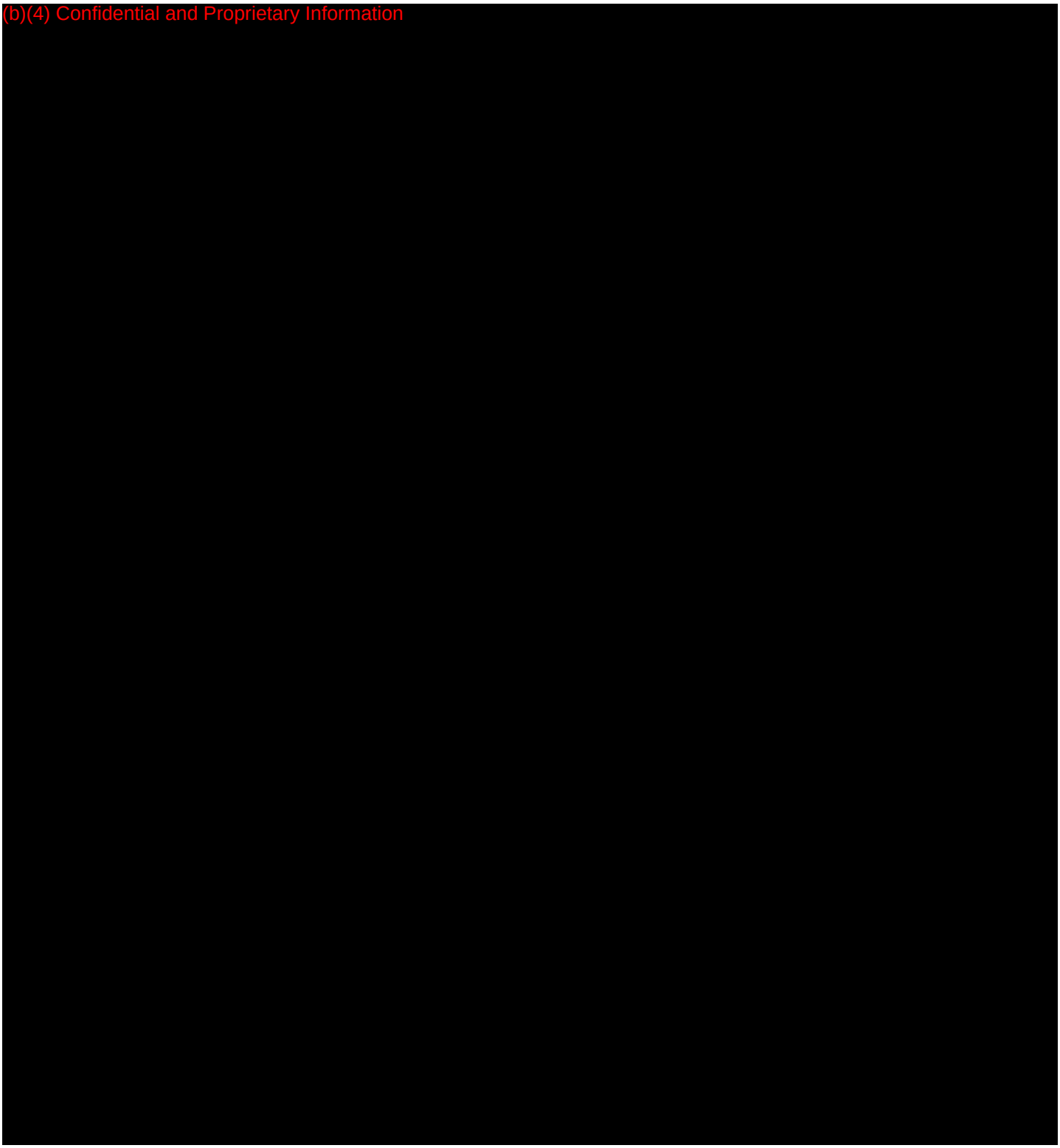


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(b)(4) Confidential and Proprietary Information

[redacted]

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device


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Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 180 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 180 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm.

The requested information should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact me by email at Samuel.Shimp@fda.hhs.gov or by phone at (301) 796-6610. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016


*Contains Nonbinding Recommendations*

Print Form

# Acceptance Checklist for Special 510(k)s

**(Should be completed within 15 days of DCC receipt)**

The following information is not intended to serve as a comprehensive review.

510(k) #: K131482 Date Received by DCC: May 23, 2013

Lead Reviewer: Samuel Shimp, Ph.D.

Branch: NNDB Division: DNPMD Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

## Special 510(k) Criteria

The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.

| | Yes | No |
|---|---|---|
| **1) 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.** | X | |
| Comments? | | |
| **2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).** | X | |
| Comments? | | |
| **3) Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).** | X | |
| Comments? | | |
| **4) The submission includes only summary-level information (i.e., NO test reports with performance data).** *Note that if performance data are provided and are conducted under design validation (21 CFR 820.30(g)), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.* | | X |
| Comments? The submission was not limited to only summary-level information. The submission included the full test reports for the Design Verification and Validation testing (appendix 6) and the full test reports for the Biocompatibility testing (appendix 7). Furthermore two new tests are used to validate the design and one of the existing tests has new testing criteria/measurement methods. | | |

**Does the submission meet all 4 criteria above?**

- ○ Yes, submission meets criteria for a Special 510(k). Continue with the remainder of this checklist below.
- ◉ No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist; convert to a Traditional using the form below and apply the Traditional checklist.

# Form for Converting a Special 510(k) to a Traditional or Abbreviated 510(k)

Records processed under FOIA Request #2015-6024, Released by CDRH on 09-28-2016.

Note: Please send this to 510k Staff electronically. You do not need anyone to sign this in person.

Conversion Instructions

510(k) #: K131482

Date Received by DCC: May 23, 2013

Lead Reviewer: Samuel Shimp, Ph.D.

Device Name: Sofia Distal Access Catheter

☐ Change in Indications for Use (please list old and new indications below)

☐ Change in Technology (select one):

- ☐ We have not seen this change before in this device type.
- ☐ We have seen this change before in this device type, but we need to see the data (please provide a brief statement below regarding why summary data/risk analysis are insufficient)

☒ Other (e.g. submission included unsolicited data or sponsor is modifying a device that is not their own - please specify below)

The submission included unsolicited data including the full reports for design verification and validation as well as full reports for biocompatibility. Furthermore two new tests are used to validate the design and one of the existing tests has new testing criteria/ measurement methods, which indicate that the predicate's design controls do not adequately cover the new device.

**Digital Signature Concurrence Table**

| | |
|---|---|
| Reviewer Sign-Off | Samuel K. Shimp III 2013.06.04 15:08:37 -04'00' |
| Branch Chief Sign-Off | Quynh T. Hoang -S 2013.06.04 16:54:26 -04'00' |
| Division Sign-Off | Victor Krauthamer -S 2013.06.04 17:33:36 -04'00' |

Records processed under FOIA Request #2013-6024; Released by CDRH on 09-26-2016.


*Contains Nonbinding Recommendations*

Print Form

# Acceptance Checklist for Traditional 510(k)s

**(Should be completed within 15 days of DCC receipt)**

The following information is not intended to serve as a comprehensive review.

510(k) #: K131482 Date Received by DCC: May 23, 2013

Lead Reviewer: Samuel Shimp, Ph.D.

Branch: NNDB Division: DNPMD Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

## Preliminary Questions

| Answers in the shaded blocks indicate consultations with Center advisor is needed | Yes | No |
|---|---|---|
| **1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?**<br>If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No." | X | |
| Comments? | | |
| **2. Is the application with the appropriate Center?**<br>If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No." | X | |
| Comments? | | |
| **3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:**<br>a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?<br>b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ?<br>If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination.<br>If the answer to either question is no, mark "No." If there was no RFD, skip this question. | | |
| Comments? | | |
| **4) Is this device type eligible for a 510(k) submission?**<br>If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No." | X | |
| Comments? | | |

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

| | | |
|---|---|---|
| **5) Is there a pending PMA for the same device with the same indications for use?**<br>If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action. | | X |
| Comments? | | |
| **6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?**<br>If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm | | X |
| Comments? | | |

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Records processed under FOIA Request #2015-6024, Released by CDRH on 09-26-2016.

## Organizational Elements

*Failure to include these items alone generally should not result in an RTA designation.*

| | Yes | No |
|---|---|---|
| 1) Submission contains a Table of Contents | X | |
| 2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.) | X | |
| 3) All pages of the submission are numbered. | X | |
| 4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special) | X | |
| Comments? | | |

Records processed under FOIA Request #2015-6024, Released by CDRH on 09-26-2016.

# Elements of a Complete Submission (RTA Items)

## (21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

**Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.**

| - Any "No" answer will result in a "Refuse to Accept" decision.<br>- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | No | N/A | Comment |
|---|---|---|---|---|
| **A. Administrative** | | | | |
| 1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.) | X | | | |
| 2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter): | X | | | |
| a) Device trade name or proprietary name | X | | | |
| b) Device common name | X | | | |
| c) Device class and panel or<br>Classification regulation or<br>Statement that device has not been classified with rationale for that conclusion | X | | | |
| 3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109). | X | | | |
| 4) Submission contains 510(k) Summary or 510(k) Statement | X | | | |
| a) Summary contains all elements per 21 CFR 807.92 *(See also 510(k) Summary Checklist)* | X | | | |
| b) Statement contains all elements per 21 CFR 807.93 | | | X | |
| 5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format.* | X | | | |
| 6) Submission contains Class III Summary and Certification. *See recommended content.* | | | X | |
| 7) Submission contains clinical data | | | X | |
| 8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed. | X | | | X |
| Comments?<br>Section I of form 3514 (Utilization of Standards) was not completed and no standards were identified. However, several standards were referenced in the submission and form 3654 was provided for several standards.<br><br>This is provided as a comment and not a deficiency that warrants a refusal to accept. | | | | |
| 9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device. | | X | | X |
| a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic. | | X | | |

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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## Elements of a Complete Submission (RTA Items)

## (21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

**Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.**

| - Any "No" answer will result in a "Refuse to Accept" decision.<br>- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | No | N/A | Comment |
|---|---|---|---|---|
| Comments? The submission does not state whether or not there were prior submissions. Section F of form 3514 was left blank which is not adequate for declaring that there were no prior submissions. The firm should provide a statement declaring whether or not there were prior submissions related to the subject device. However, the reviewer is familiar with these devices from this firm and given the nature of the submission being submitted as a special 510(k), it is not believed this device had a prior submission.<br><br>This deficiency is the only deficiency found during the RTA review. Since this is the only deficiency I recommend accepting the submission (RTAA). | | | | |

## B. Device Description

| | | | | |
|---|---|---|---|---|
| 10) | | | | |
| a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement. | | | X | |
| b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. | X | | | |
| 11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including: | | | | |
| a) A description of the principle of operation and mechanism of action for achieving the intended effect. | X | | | |
| b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient. | | | | |
| c) A list and description of each device for which clearance is requested. | X | | | |
| 12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions. | X | | | |
| 13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system | | | | |
| a) Submission includes a list of all components and accessories to be marketed with the subject device. | X | | | |
| b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory. | X | | | |
| c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. | | | X | |

## C. Substantial Equivalence Discussion

| | | | | |
|---|---|---|---|---|
| 14) Submitter has identified a predicate device. | X | | | |

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## Elements of a Complete Submission (RTA Items)

## (21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

**Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.**

| - Any "No" answer will result in a "Refuse to Accept" decision.<br>- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | No | N/A | Comment |
|---|---|---|---|---|
| a) Predicate's 510(k) number, trade name, and model number (if applicable) provided.<br>For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding* documenting preamendment status *is available online.* | X | | | |
| b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing. | X | | | |
| 15) Submission includes a comparison of the following for the predicate(s) and subject device | | | | |
| a) Indications for Use | X | | | |
| b) Technology, including features, materials, and principles of operation | X | | | |
| 16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate ), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)) | X | | | |
| **D. Proposed Labeling (see also 21 CFR part 801)** | | | | |
| If *in vitro* diagnostic (IVD) device, criteria 17, 18, & 19 may be omitted. | | | | |
| 17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use. | X | | | |
| a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided). | X | | | |
| b) Submission includes directions for use that<br>- include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND<br>- includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D | X | | | |
| 18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements] | X | | | |
| 19) General labeling provisions | | | | |
| a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1). | X | | | |
| b) Labeling includes device common or usual name. (21 CFR 801.61) | X | | | |
| 20) | | | | |
| a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirements | | | X | |

Questions? Contact FOIA@CDRH.FDA.HHS.gov or SPECIFIC_REQUESTS@fda.hhs.gov or call 301-796-8118.

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## Elements of a Complete Submission (RTA Items)

## (21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

**Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.**

| - Any "No" answer will result in a "Refuse to Accept" decision.<br>- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | No | N/A | Comment |
|---|---|---|---|---|
| b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. | | | X | |
| c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. | | | X | |
| 21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. | | | X | |

## E. Sterilization

| | | | | |
|---|---|---|---|---|
| If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist. | | | | |
| Submission states that the device and/or accessories are: (one of the below must be checked) | | | | |
| X provided sterile | | | | |
| provided non-sterile but sterilized by the end user | | | | |
| non-sterile when used | | | | |
| Information regarding the sterility status of the device is not provided. | | | | |
| This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. | | | | |
| 22) Assessment of the need for sterilization information | | | | |
| a) Identification of device, and/or accessories, and/or components that are provided sterile. | X | | | |
| b) Identification of device, and/or accessories, and/or components that are end user sterilized. | | | X | |
| c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided. | | | X | |
| 23) If the device, and/or accessory, and/or a component is provided sterile: | | | | |
| a) Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.). | X | | | |
| b) A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.* | X | | | |
| c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. | X | | | |

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## Elements of a Complete Submission (RTA Items)

## (21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

**Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.**

| - Any "No" answer will result in a "Refuse to Accept" decision.<br>- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | No | N/A | Comment |
|---|---|---|---|---|
| d) Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.) | X | | | |
| e) Sterility Assurance Level (SAL) is stated. | X | | | |
| 24) If the device, and/or accessory, and/or a component is end user sterilized: | | | X | |
| 25) | | | | |
| a) If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement. | | | X | |
| b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. | | | X | |
| c) If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. | | | X | |
| **F. Shelf Life** | | | | |
| 26) Proposed shelf life/expiration date stated | X | | | |
| 27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable. | X | | | |
| 28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness. | X | | | |
| **G. Biocompatibility** | | | | |
| If IVD device, select "N/A" and the below criteria will be omitted from checklist. | | | | |
| Submission states that there: (one of the below must be checked) | | | | |
| X are direct or indirect (e.g., through fluid infusion) patient-contacting components. | | | | |
| are no direct or indirect (e.g., through fluid infusion) patient-contacting components. | | | | |
| Information regarding the patient contact status of the device is not provided. | | | | |
| This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. | | | | |
| 29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present | X | | | |

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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## Elements of a Complete Submission (RTA Items)

## (21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

**Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.**

| - Any "No" answer will result in a "Refuse to Accept" decision.<br>- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | No | N/A | Comment |
|---|---|---|---|---|
| 30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.) | X | | | |
| 31) Biocompatibility assessment of patient-contacting components<br>Submission includes:<br>Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR<br>a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate). | X | | | |
| **H. Software** | | | | |
| Submission states that the device: (one of the below must be checked) | | | | |
| does contain software/firmware. | | | | |
| X does not contain software/firmware. | | | | |
| Information regarding whether the device contains software is not provided. | | | | |
| This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. | | | | |
| **I. EMC and Electrical Safety** | | | | |
| Submission states that the device: (one of the below must be checked) | | | | |
| does require EMC and Electrical Safety evaluation. | | | | |
| X does not require EMC and Electrical Safety evaluation. | | | | |
| Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided. | | | | |
| This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. | | | | |
| **J. Performance Data - General**<br>If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K. | | | | |
| 36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence. | X | | | |
| 37) | | | | |
| a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. | X | | | |

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## Elements of a Complete Submission (RTA Items)

## (21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

**Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.**

| - Any "No" answer will result in a "Refuse to Accept" decision.<br>- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | No | N/A | Comment |
|---|---|---|---|---|
| b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. | | | X | |
| c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. | | | X | |
| 38) If literature is referenced in the submission, submission includes: | | | X | |
| 39) For each completed nonclinical (i.e., animal) study conducted | | | X | |

## K. Performance Characteristics - In Vitro Diagnostic Devices Only

**(Also see 21 CFR 809.10(b)(12))**

Submission states that the device: (one of the below must be checked)

| | |
|---|---|
| | is an in vitro diagnostic device. |
| X | is not an in vitro diagnostic device. |

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**Decision:** (•) Accept ( ) Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

**Digital Signature Concurrence Table**

| | |
|---|---|
| Reviewer Sign-Off | Samuel K. Shimp III 2013.06.04 12:30:43 -04'00' |
| Branch Chief Sign-Off (digital signature optional)* | Quynh T. Hoang -S 2013.06.04 16:47:55 -04'00' |
| Division Sign-Off (digital signature optional)* | Victor Krauthamer -S 2013.06.04 17:31:22 -04'00' |

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

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*Contains Nonbinding Recommendations*

Print Form

# Acceptance Checklist for Special 510(k)s

**(Should be completed within 15 days of DCC receipt)**

The following information is not intended to serve as a comprehensive review.

510(k) #: K131482 Date Received by DCC: May 23, 2013

Lead Reviewer: Samuel Shimp, Ph.D.

Branch: NNDB Division: DNPMD Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

## Special 510(k) Criteria

The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.

| | Yes | No |
|---|---|---|
| **1) 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.** | X | |
| Comments? | | |
| **2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).** | X | |
| Comments? | | |
| **3) Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).** | X | |
| Comments? | | |
| **4) The submission includes only summary-level information (i.e., NO test reports with performance data).** *Note that if performance data are provided and are conducted under design validation (21 CFR 820.30(g)), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.* | X | |
| Comments? | | |

**Does the submission meet all 4 criteria above?**

- (●) Yes, submission meets criteria for a Special 510(k). Continue with the remainder of this checklist below.
- ( ) No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist; convert to a Traditional using the form below and apply the Traditional checklist.

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## Organizational Elements

*Failure to include these items alone generally should not result in an RTA designation.*

| | Yes | No |
|---|---|---|
| 1) Submission contains a Table of Contents | X | |
| 2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.) | X | |
| 3) All pages of the submission are numbered. | X | |
| 4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special) | X | |
| Comments? | | |

Records processed under FOIA Request #2015-6024, Released by CDRH on 09-26-2016.

# Elements of a Complete Submission (RTA Items)

## (21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

**Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.**

| - Any "No" answer will result in a "Refuse to Accept" decision.<br>- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | No | N/A | Comment |
|---|---|---|---|---|
| **A. Administrative** | | | | |
| 1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.) | X | | | |
| 2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter): | X | | | |
| a) Device trade name or proprietary name | X | | | |
| b) Device common name | X | | | |
| c) Device class and panel or<br>Classification regulation or<br>Statement that device has not been classified with rationale for that conclusion | X | | | |
| 3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109). | X | | | |
| 4) Submission contains 510(k) Summary or 510(k) Statement | X | | | |
| a) Summary contains all elements per 21 CFR 807.92 *(See also 510(k) Summary Checklist)* | X | | | |
| b) Statement contains all elements per 21 CFR 807.93 | | | X | |
| 5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format.* | X | | | |
| 6) Submission contains Class III Summary and Certification. *See recommended content.* | | | X | |
| 7) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed. | X | | | X |
| Comments? Section I of form 3514 (Utilization of Standards) was not completed and no standards were identified. However, several standards were referenced in the submission and form 3654 was provided for several standards.<br>This is provided as a comment and not a deficiency that warrants a refusal to accept. | | | | |
| 8) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device. | | X | | X |
| a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic. | | X | | |
| Comments? The submission does not state whether or not there were prior submissions. Section F of form 3514 was left blank which is not adequate for declaring that there were no prior submissions. You need to provide a statement declaring whether or not there were prior submissions related to the subject device. | | | | |

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024, Released by CDRH on 09-26-2016.

## Elements of a Complete Submission (RTA Items)

## (21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

**Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.**

| - Any "No" answer will result in a "Refuse to Accept" decision.<br>- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | No | N/A | Comment |
|---|---|---|---|---|
| **B. Device Description** | | | | |
| 9) | | | | |
| a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement. | | | X | |
| b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. | X | | | |
| 10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including: | | | | |
| a) A description of the principle of operation and mechanism of action for achieving the intended effect. | X | | | |
| b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient. | X | | | |
| c) A list and description of each device for which clearance is requested. | X | | | |
| 11) A description of all device modification(s) including rationale for each modification. | X | | | |
| 12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions. | X | | | |
| 13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system | | | | |
| a) Submission includes a list of all components and accessories to be marketed with the subject device. | X | | | |
| b) Submission includes a description (as detailed in item 10(a) and (b) and 12 above) of each component or accessory. | X | | | |
| c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. | | | X | |
| **C. Substantial Equivalence Discussion** | | | | |
| 14) Submitter has identified a predicate device. | X | | | |
| a) Predicate's 510(k) number, trade name, and model number (if applicable) provided.<br>For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online.* | X | | | |
| b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing. | X | | | |
| 15) Submission includes a comparison of the following for the predicate(s) and subject device: | | | | |

Questions? Contact FDA/CDRH/OIR/DIDP at RADAC@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024, Released by CDRH on 09-20-2016.

## Elements of a Complete Submission (RTA Items)

## (21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

**Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.**

| - Any "No" answer will result in a "Refuse to Accept" decision.<br>- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | No | N/A | Comment |
|---|---|---|---|---|
| a) Indications for Use | X | | | |
| b) Technology, including features, materials, and principles of operation | X | | | |
| 16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate ), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)) | X | | | |

## D. Design Control Activities

| | | | | |
|---|---|---|---|---|
| 17) Design Control Activities Summary includes all of the following: | | | | X |
| a) Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components AND the results of the analysis. | X | | | |
| b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria. | X | | | |
| c) Declaration of conformity with design controls, including:<br>*All 3 must be present to answer "Yes."*<br>*i.* Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met.<br>*ii.* Statement that manufacturing facility is in conformance with design control procedure requirements as specified in *21 CFR 820.30*.<br>*iii.* Statement is signed by the individual responsible for these activities. | X | | | |

Comments? You provide a Design Control Activities Summary in which you identify the verification and validation activities required based on the Risk Analysis. We recommend that you provide with the summary a justification for why the design controls in the predicate device are sufficient to verify and validate the changes implemented in the subject 510(k) device. For example, you specify that the hydophilic coating in the new device is similar to that used in the Headway DUO (K120917) but is different from the cited predicate K082385. Please be aware that if the design control activities for the predicate are not sufficient to verify and validate the changes implemented in the subject device, a traditional 510(k) submission will be required.

We also recommend that for each design control activity you perform for the subject device you identify the corresponding design control activity performed for the predicate device and whether or not the performance criteria for that has been changed. Note that changes in performance criteria may also warrant a conversion to traditional 510(k).

These comments are provided for your convenience but are not deficiencies that warrant a refusal to accept.

## E. Proposed Labeling (see also 21 CFR part 801)

| | | | | |
|---|---|---|---|---|
| 18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use. | X | | | X |

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-6024, Released by CDRH on 09-26-2016.

## Elements of a Complete Submission (RTA Items)

## (21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

**Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.**

| - Any "No" answer will result in a "Refuse to Accept" decision.<br>- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | No | N/A | Comment |
|---|---|---|---|---|
| a) All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified. | | X | | |
| Comments? Only a clean copy of the labeling is provided. The labeling provided does not identify any changes from the previous version of the labeling. There is no narrative description or highlighted/redlined version of the labeling to prominently identify the proposed labeling changes. | | | | |
| 19) Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s). | X | | | |

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

**Decision:** ○ Accept ◉ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

| Digital Signature Concurrence Table | |
|---|---|
| Reviewer Sign-Off | Samuel K. Shimp III 2013.06.07 14:43:56 -04'00' |
| Branch Chief Sign-Off (digital signature optional)* | Quynh T. Hoang -S 2013.06.07 15:15:06 -04'00' |
| Division Sign-Off (digital signature optional)* | |

* Branch and Division review of checklist and concurrence with with decision required. Branch and Division digital signature optional.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016


*Contains Nonbinding Recommendations*

Print Form

# Acceptance Checklist for Special 510(k)s

**(Should be completed within 15 days of DCC receipt)**

The following information is not intended to serve as a comprehensive review.

510(k) #: K131482 Date Received by DCC: Jun 12, 2013

Lead Reviewer: Samuel Shimp, Ph.D.

Branch: NNDB Division: DNPMD Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

## Special 510(k) Criteria

The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.

| | Yes | No |
|---|---|---|
| **1) 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.** | X | |
| Comments? | | |
| **2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).** | X | |
| Comments? | | |
| **3) Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).** | X | |
| Comments? | | |
| **4) The submission includes only summary-level information (i.e., NO test reports with performance data).** *Note that if performance data are provided and are conducted under design validation (21 CFR 820.30(g)), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.* | X | |
| Comments? | | |

**Does the submission meet all 4 criteria above?**

- (●) Yes, submission meets criteria for a Special 510(k). Continue with the remainder of this checklist below.
- ( ) No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist; convert to a Traditional using the form below and apply the Traditional checklist.

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## Organizational Elements

*Failure to include these items alone generally should not result in an RTA designation.*

| | Yes | No |
|---|---|---|
| 1) Submission contains a Table of Contents | X | |
| 2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.) | X | |
| 3) All pages of the submission are numbered. | X | |
| 4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special) | X | |
| Comments? | | |

Records processed under FOIA Request #2015-6024, Released by CDRH on 09-26-2016.

# Elements of a Complete Submission (RTA Items)

## (21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

**Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.**

| - Any "No" answer will result in a "Refuse to Accept" decision.<br>- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | No | N/A | Comment |
|---|---|---|---|---|
| **A. Administrative** | | | | |
| 1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.) | X | | | |
| 2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter): | X | | | |
| a) Device trade name or proprietary name | X | | | |
| b) Device common name | X | | | |
| c) Device class and panel or<br>Classification regulation or<br>Statement that device has not been classified with rationale for that conclusion | X | | | |
| 3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109). | X | | | |
| 4) Submission contains 510(k) Summary or 510(k) Statement | X | | | |
| a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist*)* | X | | | |
| b) Statement contains all elements per 21 CFR 807.93 | | | X | |
| 5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format. | X | | | |
| 6) Submission contains Class III Summary and Certification. *See recommended* content. | | | X | |
| 7) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed. | X | | | |
| 8) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device. | X | | | |
| a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic. | X | | | |
| **B. Device Description** | | | | |
| 9) | | | | |
| a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement. | | | X | |

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

Records processed under FOIA Request #2015-6024, Released by CDRH on 09-26-2016.

## Elements of a Complete Submission (RTA Items)

## (21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

**Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.**

| - Any "No" answer will result in a "Refuse to Accept" decision.<br>- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | No | N/A | Comment |
|---|---|---|---|---|
| b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. | X | | | |
| 10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including: | | | | |
| a) A description of the principle of operation and mechanism of action for achieving the intended effect. | X | | | |
| b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient. | X | | | |
| c) A list and description of each device for which clearance is requested. | X | | | |
| 11) A description of all device modification(s) including rationale for each modification. | X | | | |
| 12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions. | X | | | |
| 13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system | | | | |
| a) Submission includes a list of all components and accessories to be marketed with the subject device. | X | | | |
| b) Submission includes a description (as detailed in item 10(a) and (b) and 12 above) of each component or accessory. | X | | | |
| c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. | | | X | |
| **C. Substantial Equivalence Discussion** | | | | |
| 14) Submitter has identified a predicate device. | X | | | |
| a) Predicate's 510(k) number, trade name, and model number (if applicable) provided.<br>For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online.* | X | | | |
| b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing. | X | | | |
| 15) Submission includes a comparison of the following for the predicate(s) and subject device | | | | |
| a) Indications for Use | X | | | |
| b) Technology, including features, materials, and principles of operation | X | | | |

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## Elements of a Complete Submission (RTA Items)

## (21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

**Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.**

| - Any "No" answer will result in a "Refuse to Accept" decision.<br>- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | No | N/A | Comment |
|---|---|---|---|---|
| 16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate ), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)) | X | | | |
| **D. Design Control Activities** | | | | |
| 17) Design Control Activities Summary includes all of the following: | | | | |
| a) Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components AND the results of the analysis. | X | | | |
| b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria. | X | | | |
| c) Declaration of conformity with design controls, including:<br>*All 3 must be present to answer "Yes."*<br>*i.* Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met.<br>*ii.* Statement that manufacturing facility is in conformance with design control procedure requirements as specified in *21 CFR 820.30*.<br>*iii.* Statement is signed by the individual responsible for these activities. | X | | | |
| **E. Proposed Labeling (see also 21 CFR part 801)** | | | | |
| 18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use. | X | | | |
| a) All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified. | X | | | |
| 19) Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s). | X | | | |

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**Decision:** (•) Accept ( ) Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

| Digital Signature Concurrence Table | |
|---|---|
| Reviewer Sign-Off | Samuel K. Shimp III 2013.06.21 11:56:11 -04'00' |
| Branch Chief Sign-Off (digital signature optional)* | Quynh T. Hoang -S 2013.06.27 12:32:30 -04'00' |
| Division Sign-Off (digital signature optional)* | |

* Branch and Division review of checklist and concurrence with with decision required. Branch and Division digital signature optional.

Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016.

# COVER SHEET MEMORANDUM

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics and
Radiological Health

**From:** Reviewer Name Samuel K. Shimp III

**Subject:** 510(k) Number K131482

**To:** The Record

**Please list CTS decision code:** SE - Substantially Equivalent

☐ Refused to Accept (Note: this is considered the first review cycle. See screening checklist.)

☐ Hold (Additional Information or Telephone Hold)

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

| Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.) | YES | NO |
|---|---|---|
| Indications for Use Page *(Attach IFU)* | X | |
| 510(k) Summary or 510(k) Statement *(Attach Summary or Statement)* | X | |
| Truthful and Accurate Statement *(Must be present for a Final Decision)* | X | |
| Is the device Class III? | | X |
| Does firm reference standards? (If yes, please attach Form 3654.) | X | |
| Is this a combination product? | | X |
| Is this a reprocessed single use device? (See Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices.) | | X |
| Is this device intended for pediatric use only? | | X |
| Is this a prescription device? (If both prescription & OTC, check both boxes.) | X | |
| Is clinical data necessary to support the review of this 510(k)? | | X |
| For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.) | | X |
| Does this device include an Animal Tissue Source? | | X |
| All Pediatric Patients age <= 21 | | X |
| Neonate/Newborn (Birth to 28 days) | | X |
| Infant (29 days to < 2 years) | | X |
| Child (2 years to <12 years) | | X |
| Adolescent (12 years to <18 years) | | X |
| Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or tesating, different protocol procedures, etc.) | | X |
| Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years) | | X |

| | | | |
|---|---|---|---|
| Nanotechnology | Records processed under FOIA Request #2015-6024; Released by CDRH on 09-26-2016. | | X |
| Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance) | | | X |

| | |
|---|---|
| **Regulation Number:** | 870.1250 |
| **Class:** | II |
| **Product Code:** | DQY |
| **Additional Product Codes:** | DQO |

**Digital Signature Concurrence Table**
**(Not all signatures may be required)**

| | |
|---|---|
| Branch Chief Sign-Off | Quynh T. Hoang -S<br>2013.11.21 18:25:48 -05'00' |
| Division Sign-Off | Joyce M. Whang -S<br>2013.11.22 12:17:40 -05'00' |