



Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

United States Endoscopy Group, Inc.
c/o Mr. John Howlett
British Standards Institution
Product Services
Maylands Avenue
Hemel Hempstead, Herts HP2 4SQ
UNITED KINGDOM

MAR 19 2007

Re: K070420
Trade/Device Name: BioShield® – ERCP Biopsy Valve
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: KOG
Dated: October 18, 2007
Received: February 20, 2007

Dear Mr. Howlett:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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.



Protecting and Promoting Public Health

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); good manufacturing practice requirements as set 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.

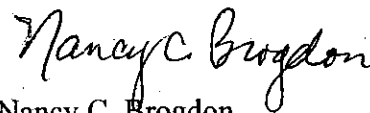
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|-----------------|----------------------------------|--------------|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: **BioShield[®] – ERCP Biopsy Valve**

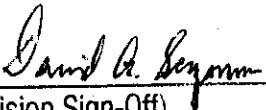
Indications for Use:

The single use BioShield[®] - ERCP biopsy valve is used to cover the opening to the biopsy/suction channel of Olympus and G5 and newer Fujinon gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, and
Radiological Devices
510(k) Number K070420



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

United States Endoscopy Group, Inc.
c/o Mr. John Howlett
British Standards Institution
Product Services
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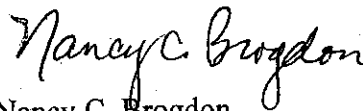
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| Other | | 240-276-0100 |

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Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: **BioShield® – ERCP Biopsy Valve**

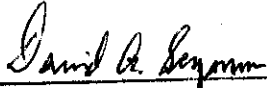
Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, and
Radiological Devices
510(k) Number K070420

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

February 22, 2007

UNITED STATES ENDOSCOPY GROUP, INC.
c/o BRITISH STANDARDS INSTITUTION
PRODUCT SERVICES
MAYLANDS AVENUE
HEMEL HEMPSTEAD,
UNITED KINGDOM HP2 4SQ
ATTN: JOHN HOWLETT

510(k) Number: K070420
Received: 20-FEB-2007
Product: BIOSHIELD-ERCP
BIOPSY VALVE, MODEL
00711138

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

Please note the following documents as they relate to 510(k) review:
1) Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". 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 (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html.
2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).
3) Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/. If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

Handwritten signature or initials, possibly 'JS' or 'MS', in black ink.

1C 070420

Tab 1 - Cover Letter Traditional 510(k)

TRADITIONAL 510(k) SUBMISSION

Submission Date: _____
(Month/dd/yyyy)

Name & Address of BSI Authorized Person:

John Howlett,
Head of BSI Medical Device Notified Body,
BSI Group, Product Services,
British Standards Institution,
Maylands Avenue,
Hemel Hempstead, Herts HP2 4SQ
UK

Phone: 011- 44-1442-278507
FAX: 011-44-1442-278575

Name & Address of BSI Technical Reviewer:

Andre Routh, PhD.,
Senior Product Expert,
BSI Product Services – Healthcare,
12110 Sunset Hills Road, Suite 200
Reston, VA 20190

Phone/FAX: 609-654-1600

Name & Address of 510(K) Submitter:

Mr. Michael Wolf,
United States Endoscopy Group,
5976 Heisley Road,
Mentor, OH 44060
USA

Date received: November 8, 2006

Device Trade Name: BioShield – ERCP Biopsy Valve

FDA Classification:

Device Class: II
Product Code: KOG
CFR Section: 21 CFR 876.1500
Classification Name: Endoscope and/or accessories

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Tab 1 - Cover Letter Traditional 510(k)

Consultation with Appropriate Branch Chief, Team Leader or Designate

Andre Routh, the BSI Technical Reviewer, spoke with Janine Morris (Supv Mechanical Engineer, DHHS/FDA/CDRH/ODE/DRARD/ULDB) on January 16, 2007 to identify relevant issues and review criteria. Dr. Routh emailed Ms. Morris on January 17, 2007 a summary of the submission. Ms. Morris replied to the email on January 17, 2007: "This looks pretty straight forward. We are a bit sensitive to things like the name of the device, "bioshield" since it can imply some type of claim. If it was in contact with the patient I would want to look and see if there was any type of coating they were adding that led them to choose this name but it doesn't seem to be the case here. I assume "bio" is referring to biopsy? Anyway we are careful about any claims including the name of the device." Andre Routh contacted US Endoscopy for a clarification of the derivation of the trade name (Note from US Endoscopy CEO Gulam Khan dated January 30, 2007 included in the submission).

BSI Recommendation Regarding Substantial Equivalence:

The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent (for the indications for use stated in the application) to the legally marketed predicate device described elsewhere in this application.

BSI Authorized Person

Signature: _____
John Howlett, Head of BSI Medical Device Notified Body

Date: _____
(Month/dd/yyyy)

BSI Technical Reviewer

Signature: _____
Andre G. Routh, PhD, Senior Product Expert

Date: _____
(Month/dd/yyyy)

FAX COVER SHEET

Phone/FAX: 609-654-1600

TO: DIANE GARCIA

FROM: ANDRE ROUTH (BSI)

DATE (dd/mm/yyyy): 21/02/2007

PAGES (inc cover page): 3

HERE IS TAB 1 FROM OUR
REVIEW OF THE US ENDOSCOPY
SUBMISSION (K070420)

Regards,

Andre Routh.

BSI

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Obst, John*

From: Garcia, Diane
Sent: Wednesday, February 21, 2007 12:30 PM
To: Obst, John*
Subject: FW: Third party

Can you do the rest?

Diane Garcia
FDA/CDRH/ODE/POS
240-276-4040 Main POS Line
240-276-4027 Direct Line
Diane.Garcia@fda.hhs.gov

From: Lee, Patti
Sent: Wednesday, February 21, 2007 12:30 PM
To: Garcia, Diane
Subject: RE: Third party

I changed the third party flag to 'Y' and it is under review. You may want to update some third party info through the data entry screens.

Patty Lee
Information Technology Specialist
OC/OM/OCIO/OIT-CDRH/SWDB
(240)276-0373

From: Garcia, Diane [<mailto:diane.garcia@fda.hhs.gov>]
Sent: Wednesday, February 21, 2007 10:53 AM
To: Lee, Patti
Subject: Third party

Patty
Can we make k070420 into a third party 510k?

Diane Garcia
FDA/CDRH/ODE/POS
240-276-4040 Main POS Line
240-276-4027 Direct Line
Diane.Garcia@fda.hhs.gov

Obst, John*

From: Garcia, Diane
Sent: Wednesday, February 21, 2007 10:28 AM
To: Obst, John*
Subject: FW: K070420 US Endoscopy

This should be all the info for the third party. Let me know the 510k number and we'll have to change the start date for this one.

*Diane Garcia
 FDA/CDRH/ODE/POS
 240-276-4040 Main POS Line
 240-276-4027 Direct Line
 Diane.Garcia@fda.hhs.gov*

From: Andre Routh [mailto:Andre.Routh@bsi-global.com]
Sent: Wednesday, February 21, 2007 10:20 AM
To: Garcia, Diane; Shulman, Marjorie G.
Cc: Morris, Janine M.; Mike Wolf; Obst, John*; Stuart, Julie (Brandi)
Subject: RE: K070420 US Endoscopy

Dear Ms. Garcia,

The box contained 4 files. Two of the files (identical) contained the data from US Endoscopy. The other two files (also identical) contained the British Standards Institution 510(k) review materials.

The BSI folders contained the following information:

US Endoscopy BioShield ERCP Biopsy Valve 510(k) Submission

| Section | Location | Check |
|--|--------------------|-------|
| 510(k) Summary (if any) | Not supplied** | X |
| Indications for Use Statement | Inside Front Cover | √ |
| Cover Letter | Tab 1 | √ |
| TOC | Tab 2 | √ |
| Letter authorizing BSI to submit the 510 (k) | Tab 3 | √ |
| Truthful and Accurate Statement | Tab 4 | √ |
| 510(k) Decision-Making Documentation | Tab 5 | √ |

| | | |
|---|-------|---|
| BSI review memorandum with supervisory sign off | Tab 6 | √ |
| Screening Checklist | Tab 7 | √ |

**** Submitter provided a 510(k) Statement**

BSI received the initial 510(k) submission from US Endoscopy on October 20, 2006. I, as BSI Technical Reviewer, actually received the file on November 8, 2006

Here are the Authorized Person, Technical Reviewer (Andre Routh), and Submitter details taken from "Tab 1 Cover Letter Traditional 510 (k)" from our (BSI) review:

Name & Address of BSI Authorized Person:

John Howlett,
 Head of BSI Medical Device Notified Body,
 BSI Group, Product Services,
 British Standards Institution,
 Maylands Avenue,
 Hemel Hempstead, Herts HP2 4SQ
 UK

Phone: 011- 44-1442-278507

FAX: 011-44-1442-278575

Name & Address of BSI Technical Reviewer:

Andre Routh, PhD.,
 Senior Product Expert,
 BSI Product Services – Healthcare,
 12110 Sunset Hills Road, Suite 200
 Reston, VA 20190

Phone/FAX: 609-654-1600

Name & Address of 510(K) Submitter:

Mr. Michael Wolf,
 United States Endoscopy Group,
 5976 Heisley Road,
 Mentor, OH 44060
 USA

Regards,

Andre Routh

Andre Routh, PhD.,
Product Expert,
BSi Product Services Healthcare
Phone/FAX: 609-654-1600
Mobile Phone: 571-239-0219
andre.routh@bsi-global.com

From: Garcia, Diane [mailto:diane.garcia@fda.hhs.gov]
Sent: Wednesday, February 21, 2007 10:00 AM
To: Andre Routh; Shulman, Marjorie G.
Cc: Morris, Janine M.; Mike Wolf; Obst, John*; Stuart, Julie (Brandi)
Subject: RE: K070420 US Endoscopy

This 510k did not include any third party information. Therefore, we could not log it into the system as a third party. That is why you received the letter asking you for the user fee. Would you please send us the entire contact information for the third party. We need contact names, addresses, phone numbers, etc.

You can fax it to 240-276-4025.

Thank you.

Diane Garcia
FDA/CDRH/ODE/POS
240-276-4040 Main POS Line
240-276-4027 Direct Line
Diane.Garcia@fda.hhs.gov

From: Andre Routh [mailto:Andre.Routh@bsi-global.com]
Sent: Wednesday, February 21, 2007 9:10 AM
To: Garcia, Diane; Shulman, Marjorie G.
Cc: Morris, Janine M.; Andre Routh; Mike Wolf
Subject: RE: K070420 US Endoscopy
Importance: High

**RE: K070420 for US Endoscopy
Traditional 510(k)
Review by Third-Party Accredited Person (British Standards
Institution)**

2/21/2007

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

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Dear Ms. Shulman and Ms. Garcia,

As a matter of great urgency, please tell me what has happened to this 510(k) submission.

Have you located it?

Have you removed the "hold" that was erroneously placed on it?

Has the submission been forwarded to the reviewer, Janine Morris, in the ODE Urology and Lithotripsy Devices Branch?

The client, US Endoscopy is, justifiably, alarmed by this breakdown in protocol and communications.

Kindly email me at andre.routh@bsi-global.com or phone me at 609-654-1600 as soon as you read this message.

This matter is extremely urgent.

Regards,

Andre Routh

Andre Routh, PhD.,
Senior Product Expert,
BSi Product Services Healthcare
Phone/FAX: 609-654-1600
Mobile Phone: 571-239-0219
andre.routh@bsi-global.com

From: Andre Routh
Sent: Thursday, February 15, 2007 6:08 PM
To: 'diane.garcia@fda.hhs.gov'
Cc: 'marjorie.shulman@fda.hhs.gov'; Paul Brooks

2/21/2007

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

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Subject: Re: K070420 US Endoscopy
Importance: High

Re: K070420

Dear Ms. Garcia,

Please let me introduce myself: I am a Technical Reviewer with the British Standards Institution (BSI). BSI is an "accredited person" under the Third Party Reviewer program.

We recently submitted a third-party reviewed Traditional 510(k) submission to FDA on behalf of the submitter, US Endoscopy.

The prospective FDA reviewer is Janine Morris, with whom I have been in contact to discuss the submission.

Today, I spoke with Mike Wolf of US Endoscopy. Mr. Wolf had received a FAX that went out over Marjorie Shulman's name informing Mr. Wolf that the PMN fee had not been received and that the submission has been placed on hold.

Regarding your question about whether or not any fees were due to FDA, please go to the following webpage:
<http://www.fda.gov/cdrh/devadvice/314a.html>

You will notice on Page 2:

| Fee Exemptions and Waivers (No Fee for These) | |
|---|---|
| Category | Exemption or Waiver |
| Third-party 510 (k) | Exempt from any FDA fee; however, the third-party does charge a fee for its review. |

In other words, no fee is due because this is a third-party reviewed 510 (k).

Additionally, Section 1 of US Endoscopy's submission consists of the CDRH PREMARKET REVIEW SUBMISSION COVERSHEET (an FDA

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webform). Section A has checked in the 510(k) box: Original Submission, Traditional and **Third Party**.

You advised me to fill out a MDUFMA cover sheet. Please follow this link to the MDUFMA website:

https://fdasfinapp8.fda.gov/OA_HTML/ibeCCTpBuyRoute.jsp

The **ONLY** box mentioning PMN is the following one: Premarket notification (510(k)); **except for third party**

There is **NO** way of getting beyond this screen.

Kindly advise me how to get beyond this seeming impasse.

Regards,

Andre Routh

Andre Routh, PhD.,
Senior Product Expert,
BSi Product Services Healthcare
Phone/FAX: 609-654-1600
Mobile Phone: 571-239-0219
andre.routh@bsi-global.com

16070420



5976 Helsey Road
Mentor OH 44061

phone 440/639-4494

fax 440/639-4495

customer service 800/769-8229

www.usendoscopy.com

18 October 2006

Via Fed Ex

Dr. Andre Routh
BSI Management Systems
12110 Sunset Hills Road, Suite 140
Reston, VA 20190

re: **510(k) Premarket Notification (Traditional)**

Dear Dr. Routh :

Enclosed please find two copies of a **510(k)** Premarket Notification submission, and a copy of the submission in electronic media on a CD. A copy of the CDRH Premarket Review Submission Cover Sheet, and 510(k) Screening Checklist are also included.

This letter authorizes British Standards Institute (BSI), in its capacity as an Accredited Person, to review the 510(k) pre-market notification that we have submitted for the BioShield® ERCP biopsy valve, to submit the 510(k) to FDA on our behalf, and to discuss its contents with FDA.

Please feel free to contact me with any questions. If I am unavailable for any reason, you may also contact either of my colleagues whose contact information is listed below.

With kindest regards,

R. Michael Wolf
Manager of Regulatory Affairs
mwolf@usendoscopy.com
800-769-8229 Ext. 378
440-639-4494 Ext. 378
216-308-2431 (mobile)

Establishment Registration Number 1528319

Additional contacts:

Mr. Dean Secrest – Executive Vice President – New Product Development – Ext. 311
Mr. Chris Kaye – Director of Engineering – Ext. 305

**FDA CDRH DMC
RECEIVED
FEB 13 2007**

K28

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510(k) SUBMISSION

BioShield® - ERCP Biopsy Valve

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| | |
|---|--|
| DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET | Form Approval OMB No. 9010-0120 Expiration Date: May 31, 2007. See OMB Statement on page 5. |
|---|--|

| | | |
|----------------------------------|----------------------------|---|
| Date of Submission 10/18/2006 | User Fee Payment ID Number | FDA Submission Document Number (if known) |
|----------------------------------|----------------------------|---|

| SECTION A TYPE OF SUBMISSION | | | | |
|--|--|---|---|--|
| PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement | PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other | PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP | 510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input checked="" type="checkbox"/> Third Party | Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify): |
| IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement | Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment | Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information | Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information | Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission): |

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 United States Endoscopy | Establishment Registration Number (if known) 1528319 | | |
| Division Name (if applicable) | Phone Number (including area code) (440) 639-4494 | | |
| Street Address 5976 Heisley Road | FAX Number (including area code) (440) 639-4495 | | |
| City Mentor | State / Province OH | ZIP/Postal Code 44060 | Country USA |
| Contact Name Mr. Michael Wolf | | | |
| Contact Title Manager of Regulatory Affairs | | Contact E-mail Address mwolf@usendoscopy.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/Postal Code | Country |
| Contact Name | | | |
| Contact Title | | Contact E-mail Address | |

| SECTION D1 | | | REASON FOR APPLICATION - PMA, PDP, OR HDE | | |
|--|---|---|---|--|--|
| <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site | <input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>) | <input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager | | | |
| <input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (<i>specify below</i>) | <input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>) | <input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment | | | |
| <input type="checkbox"/> Response to FDA correspondence: | | <input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address | | | |
| <input type="checkbox"/> Other Reason (<i>specify</i>): | | | | | |
| SECTION D2 | | | REASON FOR APPLICATION - IDE | | |
| <input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access | <input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor | <input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing | | | |
| <input type="checkbox"/> Other Reason (<i>specify</i>): | | | | | |
| SECTION D3 | | | REASON FOR SUBMISSION - 510(k) | | |
| <input checked="" type="checkbox"/> New Device | <input type="checkbox"/> Additional or Expanded Indications | <input type="checkbox"/> Change in Technology | | | |
| <input type="checkbox"/> Other Reason (<i>specify</i>): | | | | | |

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| SECTION E | | | | ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS | | | | |
|---|-----|---|--|--|--|---|--|---|
| Product codes of devices to which substantial equivalence is claimed | | | | | | | | Summary of, or statement concerning, safety and effectiveness information <input type="checkbox"/> 510 (k) summary attached <input checked="" type="checkbox"/> 510 (k) statement |
| 1 | KOG | 2 | | 3 | | 4 | | |
| 5 | | 6 | | 7 | | 8 | | |
| Information on devices to which substantial equivalence is claimed (if known) | | | | | | | | |

| | 510(k) Number | Trade or Proprietary or Model Name | Manufacturer |
|---|---------------|---|---------------------|
| 1 | K010610 | 1 Microvase Rapid Exchange Locking Device and Biopsy Cap System | 1 Boston Scientific |
| 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
 Endoscope and/or accessories

| | Trade or Proprietary or Model Name for This Device | Model Number |
|---|--|--------------|
| 1 | BioShield - ERCP Biopsy Valve | 1 00711138 |
| 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 KOG | C.F.R. Section (if applicable) 21 CFR 876.1500 | Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified |
| Classification Panel Gastroenterology/ Urology | | |

Indications (from labeling)
 The single use BioShield® - ERCP biopsy valve is used to cover the opening to the biopsy/suction channel of Olympus and G5 and newer Fujinon gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

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

| | | | | | |
|--|--|--|--|---|--|
| <input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete | | FDA Establishment Registration Number 1528319 | | <input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler | |
| Company / Institution Name United States Endoscopy | | | Establishment Registration Number 1528319 | | |
| Division Name (if applicable) | | | Phone Number (including area code) (440) 639-4494 | | |
| Street Address 5976 Heisley Road | | | FAX Number (including area code) (440) 639-4495 | | |
| City Mentor | | State / Province OH | ZIP/Postal Code 44060 | Country USA | |
| Contact Name Mr. Michael Wolf | | Contact Title Manager of Regulatory Affairs | | Contact E-mail Address mwolf@usendoscopy.com | |

| | | | | | |
|--|--|--|---|---|--|
| <input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete | | FDA Establishment Registration Number (b) (4) | | <input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler | |
| Company / Institution Name (b) (4) | | | Establishment Registration Number (b) (4) | | |
| Division Name (if applicable) | | | Phone Number (including area code) (b) (4) | | |
| Street Address (b) (4) | | | FAX Number (including area code) (b) (4) | | |
| City (b) (4) | | State / Province (b) (4) | ZIP/Postal Code (b) (4) | Country (b) (4) | |
| Contact Name (b) (4) | | Contact Title (b) (4) | | Contact E-mail Address (b) (4) | |

| | | | | | |
|---|--|---------------------------------------|--|--|--|
| <input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete | | FDA Establishment Registration Number | | <input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> 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/Postal Code | Country | |
| Contact Name | | Contact Title | | Contact E-mail Address | |

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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.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing 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:

Food and Drug Administration
 CDRH (HFZ-342)
 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

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510(k) Screening Checklist

510(k) SCREENING CHECKLIST

SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - **Do Sections 1 and 4**

Section 1: Required Elements for All Types of 510(k) submissions:

| | Present or Adequate | Missing or Inadequate |
|---|---------------------|-----------------------|
| Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual. | Present | |
| Table of Contents. | Present | |
| Truthful and Accurate Statement. | Present | |
| Device's Trade Name, Device's Classification Name and Establishment Registration Number. | Present | |
| Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified). | Present | |
| Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510] Manual. | Present | |
| Statement of Indications for Use that is on a separate page in the premarket submission. | Present | |
| Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510] Manual. | Present | |
| 510(k) Summary or 510(k) Statement. | Statement | |
| Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals. | Present | |
| Identification of legally marketed predicate device. * | Present | |
| Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).] | Not required | |
| Class III Certification and Summary. ** | Not applicable | |
| Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)] | Not applicable | |
| 510(k) Kit Certification *** | Not applicable | |

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

510(k) Screening Checklist

Sections 2 & 3 Not Required for Traditional 510(k)

Section 2: Required Elements for a SPECIAL 510(k) submission:

| | Present | Inadequate or Missing |
|---|---------|-----------------------|
| Name and 510(k) number of the submitter's own, unmodified predicate device. | | |
| A description of the modified device and a comparison to the sponsor's predicate device. | | |
| A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device. | | |
| Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device. | | |
| A Design Control Activities Summary that includes the following elements (a-c): | | |
| a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis. | | |
| b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied. | | |
| c. A Declaration of Conformity with design controls that includes the following statements: | | |
| A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities. | | |
| A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities. | | |

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

| | Present | Inadequate or Missing |
|--|---------|-----------------------|
| For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.) | | |
| For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.] | | |
| For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device. | | |
| For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device. | | |
| For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence. | | |
| Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence. | | |

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

510(k) Screening Checklist

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

| | Present | Inadequate or Missing |
|--|----------------------|-----------------------|
| a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation: | Present | |
| b) Sterilization and expiration dating information: | Present | |
| i) Sterilization process | Traditional ETO | |
| ii) Validation method of sterilization process | Present | |
| iii) SAL | 10 ⁻⁶ SAL | |
| iv) Packaging | Present | |
| v) Specify pyrogen free | Not applicable | |
| vi) ETO residues | Defined | |
| vii) Radiation dose | Not applicable | |
| viii) Traditional Method or Non-Traditional Method | Traditional ETO | |
| c) Software Documentation: | Not applicable | |

Items with checks in the "Present or Adequate" column do not require additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening ____ Yes ____ No

Reviewer: _____

Concurrence by Review Branch: _____

Date: _____

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 for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at:

<http://www.fda.gov/cdrh/modact/leastburdensome.html>

Uploaded on March 3, 2004

510(k) Premarket Notification (Traditional)

Device Information

Device Trade Name: BioShield® – ERCP Biopsy Valve
Model No. 00711138
Review Panel: Gastroenterology / Urology
Classification: Class II
Product Codes: 78 KOG
Device: Endoscope and/or Accessories
Regulation #: 21CFR Part 876.1500
Predicate device: Microvasive Rapid Exchange Locking Device and Biopsy Cap System (K010610) (Boston Scientific)

Sponsor / Manufacturer:

United States Endoscopy Group, Inc.
Establishment Registration #: 1528319

5976 Heisley Road
Mentor, OH 44060
Phone 440-639-4494
Fax 440-639-4495

Contact persons: Mr. Michael Wolf – Manager of Regulatory Affairs (Ext. 378)
Mr. Dean Secret – Executive Vice President (Ext. 311)
Mr. Chris Kaye – Director of Engineering (Ext. 305)

Contract Sterilizer:

(b)(4)



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Device Description:

This device is a single use/disposable cap which is used to cover the biopsy/suction channel of endoscopes during ERCP (endoscopic retrograde cholangiopancreatography) and other endoscopic procedures. It provides access to the endoscope's working channel, minimizes leakage of biomaterial and other fluids during insufflation and instrument exchange, and allows for irrigation. (b) (4)

(b)(4)

(b)(4) . The device weighs approximately 3.1 grams.

Device drawings are provided in Section 7 of this submission.

Indications For Use:

Please see Section 4 of this submission.

Table 1: Design and Use of the Device

| Question | YES | NO |
|--|-----|----|
| Is the device intended for prescription use (21 CFR 801 Subpart D)? ^A | X | |
| Is the device intended for over-the-counter use (21 CFR 807 Subpart C)? ^A | | X |
| Does the device contain components derived from a tissue or other biologic source? | | X |
| Is the device provided sterile? | X | |
| Is the device intended for single use? | X | |
| Is the device a reprocessed single use device? | | X |
| If yes, does this device type require reprocessed validation data? | - | - |
| Does the device contain a drug? | | X |
| Does the device contain a biologic? | | X |
| Does the device use software? | | X |
| Does the submission include clinical information? | | X |
| Is the device implanted? | | X |

Indications for Use

510(k) Number (if known): _____

Device Name: **BioShield® – ERCP Biopsy Valve**

Indications for Use:

The single use BioShield® - ERCP biopsy valve is used to cover the opening to the biopsy/suction channel of Olympus and G5 and newer Fujinon gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

PREMARKET NOTIFICATION STATEMENT

510(K) STATEMENT

(As required by 21 CFR 807.93)

I certify that, in my capacity as Manager of Regulatory Affairs for United States Endoscopy Group, Inc., I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

R. Michael Wolf

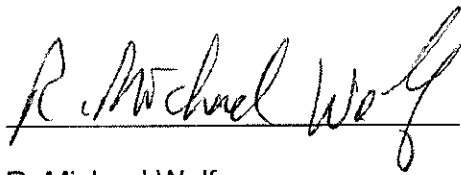
R. Michael Wolf

Date: 18 october 2006

510(k) number: New Submission

Truthful and Accurate Statement

I certify that, in my capacity as Manager of Regulatory Affairs for US Endoscopy Group, Inc., I believe to the best of my knowledge, that all data and information submitted in this pre-market notification are truthful and accurate and that no material fact has been omitted.



R. Michael Wolf

Date: 18 October 2006

510(k) number: New Submission

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Records processed under FOIA Request # 2015-4314; Released by CDRH on 03-10-2016

Records processed under FOIA Request # 2015-4314; Released by CDRH on 03-10-2016

Records processed under FOIA Request # 2015-4314; Released by CDRH on 03-10-2016

COMPARISON WITH PREDICATE DEVICE

Device: US Endoscopy BioShield® - ERCP Biopsy Valve

Predicate device: Boston Scientific Microvase Rapid Exchange Locking Device and Biopsy Cap System (K010610)

Similarities with the predicate device








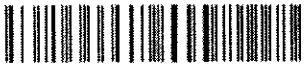






The BioShield – ERCP Biopsy Valve has the following similarities with the predicate device identified above:

- BioShield – ERCP biopsy valve and the predicate device have the same intended use. That is, they are intended to cover the biopsy port in gastrointestinal endoscopes (also commonly called the biopsy channel, suction channel, or working channel of the scope) in order to seal off this channel to minimize leakage of insufflation and fluids during endoscopic procedures.
- These devices allow for the passage of diagnostic and therapeutic devices into and out of the biopsy channel of the endoscope via slits or small openings in the body of the biopsy valve and/or in the lid or cap.
- The BioShield – ERCP and the predicate device are similar in design, employing mechanical seal features that minimize opportunities for leakage of air and fluids.
- The BioShield – ERCP and the predicate device are very similar in size and geometry, owing to the fact that they must attach securely to the same fixtures, i.e. the biopsy port of similarly designed endoscopes, and must allow for the passage of the same types of devices.
- The BioShield – ERCP and the predicate device are constructed of similar polymer materials. The BioShield – ERCP is constructed of a (b) (4) . The predicate device is constructed of silicone rubber or other polymers which give them the combination of properties such as strength and elasticity that enable them to fulfill their intended use.
- The BioShield – ERCP and the predicate device are offered sterile.
- The BioShield – ERCP and the predicate device are for single patient use and are disposable.

Differences between the BioShield – ERCP and the predicate device

- The materials used in construction of the devices are not exactly the same, although they are all polymers with similar properties.
- The external and internal geometry of the BioShield – ERCP are somewhat different from the predicate device, owing to different approaches to the minimization of leakage under challenging procedural conditions.
- The BioShield – ERCP does not currently employ any external features for locking of guidewires or other devices. The Microvase Rapid Exchange Locking Device and Biopsy Cap System does include these features.

The BioShield – ERCP biopsy valve is, in our opinion, substantially equivalent to the predicate device.

| | | | |
|--|--|---|--|
|  | REF |  | 00711138 |
| | | | LOT 123456 |
| | | |  2009.10 |
| | | |  2006.10 |
| <p>BioShield® – ERCP</p> | | | |
| STERILE EO |  |  |  |
| REF | Richard J. Edmonds, Managing Director Diamed Lumley Close, Thiesk North Yorkshire, England YO73TD Phone - 44-1845-526600 Fax - 522199 | | Rx Only (U.S.A.) MADE IN U.S.A. |
| <p>See package insert for explanation of symbols. Voir la description des symboles sur la notice. Symbolerklärung: siehe Packungsbeilage Per la spiegazione dei simboli, leggere il foglietto illustrativo. Encontrará una explicación de los símbolos en el folleto del envase. Consultar o folheto informativo para obter uma explicação dos símbolos. Der er en forklaring af symbolerne i indlægssedlen. Zie bijsluiter voor verklaring van symbolen. Sembollerin açıklamasını için prospektüse bakın.</p> | | | |
|  <p>*+H788007111381H*</p>  <p>*+33000251009123456HB*</p> | | | |
|  | REF |  | 00711138 |
| <p>BioShield® – ERCP</p> | | | |
|  | | LOT | 123456 |
|  | |  | 2009.10 |
| www.usendoscopy.com | | 007123 Rev. A | 0001 |



BioShield® – ERCP

Reorder No. 00711138

INSTRUCTIONS FOR USE



Rx Only (U.S.A.)

Intended Use:

The single use **BioShield® - ERCP** valve is used to cover the opening to the biopsy/suction channel of Olympus® and G5 series and newer Fujinon® gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port throughout endoscopic procedures and provides access for irrigation.

Warnings and Precautions:

This disposable medical device is not intended for reuse. Any institution, practitioner, or third party who reprocesses, refurbishes, remanufactures, resterilizes, and or reuses this disposable medical device must bear full responsibility for its safety and effectiveness.

Contraindications:

Contraindications include those specific to any endoscopic procedure.

Pre-Use Instructions:

Prior to clinical use you should familiarize yourself with the device.

- Read the "Instructions for Use."

Instructions for Use:

1. Open the sterile package and visually inspect the **BioShield® - ERCP** valve. If any abnormality is detected that might prohibit appropriate working condition, do not use.
2. Securely place the **BioShield® - ERCP** valve onto the biopsy/suction channel opening of Olympus® and G5 series and newer Fujinon® gastrointestinal endoscopes.

Product Disposal:



After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Issued Date: October 2006

Warning:

An issued or revision date for these instructions is included for the user's information. In the event that two years have elapsed between this date and product use, the user should contact US Endoscopy to determine if additional information is available.

Made in the U.S.A.

BioShield® is a registered trademark of US Endoscopy
Olympus® is a registered trademark of Olympus Optical Co., Ltd.
Fujinon® is a registered trademark of Fuji Film Co., Ltd.



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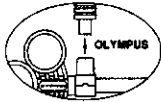
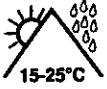
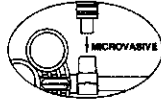



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Explanation of symbols used on Labels and Instructions For Use

| | | | |
|--|---|---|---|
| Use By |  | Sterilized by Ethylene Oxide | STERILE EO |
| Contents |  | Non-Sterile | NON-STERILE |
| Reference | REF | Single Use Only |  |
| Lot | LOT | Do Not Re-Sterilize |  |
| Date of Manufacture |  | Latex Free |  |
| Length |  | Read instructions prior to using this product |  |
| Greater Than or Equal To | \geq | Less Than or Equal To | \leq |
| Authorized Representative in the European Community | EC REP | For use with Olympus™ active cord |  |
| Store at controlled room temperature |  | For use with Microvasive™ active Cord |  |
| I.D. |  | O.D. |  |
| Do not use if packaging or product damage is evident. Contents are sterile if package is unopened and undamaged. | | |  |
| Federal law (U.S.A.) restricts this device to sale, distribution and use by, or on the order of, a physician. | | | Rx Only (U.S.A.) |

Sterilization Information

The BioShield® – ERCP biopsy valve will be offered in sterile condition. The device will be sterilized using ETO gas. Our contract sterilizer will attain 10^{-6} sterility assurance level (SAL). The method of validation is the AAMI overkill method. The ETO residual limits are listed below. The package container will be a Tyvek/mylar pouch. All sterilization procedures conform with AAMI standards for sterilization of medical devices.

Our contract sterilizer is:

(b)(4)



(b) (4)



The shelf life of the device is three (3) years. Expiration date information that reflects this shelf life is indicated clearly on the device labeling. An example of the device labeling appears in Section 9 of this submission.

The device and its packaging have been validated per AAMI standard 11135.

MATERIALS BIOCOMPATIBILITY REVIEW

Date: 10/18/2006
Review By: C. J. Kaye
Product #: 00711138

1. Device body contact requirement classification as identified using ISO-10993 Standard Biological Evaluation of Medical Devices:

External Communicating Device, Blood Path, Indirect, Limited Contact.

2. Device Bill of Materials (Attach Copy) Rev. N/A (see attached Summary)

3. Do all Materials that will contact the body directly or indirectly have certification that supports the contact requirements of ISO Standard?

Yes. No Direct Contact. Materials with potential indirect contact are:

(b) (4) Both materials meet the requirements of the ISO Standard.

4. Do all adhesives, or other materials that will contact the body directly or indirectly used in the manufacture of the device have certification that supports the contact requirements of ISO Standard?

Yes. Adhesive utilized is Loctite 3922 and this material meets the requirements of the ISO Standard.

5. Are there any manufacturing processes that can affect the biocompatibility of the materials?



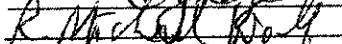

No.

6. Results/ Conclusion:

The materials /processes used in the 00711138 device meets the requirements of the ISO Standard.

Approvals

Date

| | | |
|----------------------|---|----------|
| Quality |  | 10-18-06 |
| Manufacturing |  | 10-18-06 |
| New Prod Development |  | 10/18/06 |
| Regulatory |  | 10-18-06 |

**BILL OF MATERIALS
SUMMARY FOR ERCP VALVE**

**COMPONENT LIST TO CORRESPOND TO DRAWING: 00711138
(ERCP Valve, Olympus)**



(b)(4)

(b)(4)

Biocompatibility Test Reports:

- 06T_45733_01
- 06T_45733_02
- 06T_45733_03
- 06T_45733_04
- 06T_45733_05
- 06T_45733_06

No direct Patient Contact.

Loctite, Adhesive 3922 used for bonding.
Material has established history of use on US Endoscopy BioShields,
P/N711133.

No direct patient contact.

Alcohol, Isopropyl, 91% used as assembly aid (cleaning).
Component Item P/N 340024, also with established history of use on US
Endoscopy BioShields, P/N711133

No Direct Patient Contact.

Records processed under FOIA Request # 2015-4314; Released by CDRH on 03-10-2016

Records processed under FOIA Request # 2015-4314; Released by CDRH on 03-10-2016

Records processed under FOIA Request # 2015-4314; Released by CDRH on 03-10-2016

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Inside Front Cover – Indications for Use

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: **BioShield® – ERCP Biopsy Valve**

Indications for Use:

The single use BioShield® - ERCP biopsy valve is used to cover the opening to the biopsy/suction channel of Olympus and G5 and newer Fujinon gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Tab 1 - Cover Letter Traditional 510(k)

TRADITIONAL 510(k) SUBMISSION

Submission Date: _____
(Month/dd/yyyy)

Name & Address of BSI Authorized Person:

John Howlett,
Head of BSI Medical Device Notified Body,
BSI Group, Product Services,
British Standards Institution,
Maylands Avenue,
Hemel Hempstead, Herts HP2 4SQ
UK

Phone: 011- 44-1442-278507
FAX: 011-44-1442-278575

Name & Address of BSI Technical Reviewer:

Andre Routh, PhD.,
Senior Product Expert,
BSI Product Services – Healthcare,
12110 Sunset Hills Road, Suite 200
Reston, VA 20190

Phone/FAX: 609-654-1600

Name & Address of 510(K) Submitter:

Mr. Michael Wolf,
United States Endoscopy Group,
5976 Heisley Road,
Mentor, OH 44060
USA

Date received: November 8, 2006

Device Trade Name: BioShield – ERCP Biopsy Valve

FDA Classification:

Device Class: II
Product Code: KOG
CFR Section: 21 CFR 876.1500

Device: Endoscope And/or Accessories

OK
Feb 09, 2007.

RECEIVED
FEB 12 2007
FDA CDRH DMC

Tab 1 - Cover Letter Traditional 510(k)

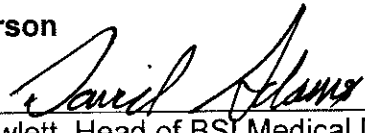
Consultation with Appropriate Branch Chief, Team Leader or Designate

Andre Routh, the BSI Technical Reviewer, spoke with Janine Morris (Supv Mechanical Engineer, DHHS/FDA/CDRH/ODE/DRARD/ULDB) on January 16, 2007 to identify relevant issues and review criteria. Dr. Routh emailed Ms. Morris on January 17, 2007 a summary of the submission. Ms. Morris replied to the email on January 17, 2007: "This looks pretty straight forward. We are a bit sensitive to things like the name of the device, "bioshield" since it can imply some type of claim. If it was in contact with the patient I would want to look and see if there was any type of coating they were adding that led them to choose this name but it doesn't seem to be the case here. I assume "bio" is referring to biopsy? Anyway we are careful about any claims including the name of the device." Andre Routh contacted US Endoscopy for a clarification of the derivation of the trade name (Note from US Endoscopy CEO Gulam Khan dated January 30, 2007 included in the submission).

BSI Recommendation Regarding Substantial Equivalence:

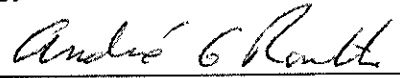
The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent (for the indications for use stated in the application) to the legally marketed predicate device described elsewhere in this application.

BSI Authorized Person

Signature: 
John Howlett, Head of BSI Medical Device Notified Body

Date: Feb 09, 2007
(Month/dd/yyyy)

BSI Technical Reviewer

Signature: 
Andre G. Routh, PhD, Senior Product Expert

Date: Feb 07, 2007
(Month/dd/yyyy)

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January 30, 2007

Mike Wolf
Regulatory Affairs
US Endoscopy

Dear Mike:

As we discussed, here is additional information regarding the BioShield:

1. Many endoscopes have an accessory port. This is often termed a "biopsy port" based on the tools inserted.
2. The accessory or biopsy ports need some means of closing them during the procedure and a means of forming a tight seal when one of the tools is inserted into the port.
3. Valves placed on the biopsy ports are commonly referred to as "biopsy port caps" or "biopsy valves."
4. I recall that the "bio" part of BioShield is derived from these common terms and generally trying to combine the prefix "bio" with something like the term "cap" or "valve".
5. The "shield" part of BioShield comes from the capping function that all biopsy port caps typically provide.
6. The BioShield does not contact the patient.
7. We do not intend the name BioShield to imply any biological action. It is simply a physical barrier to close off the accessory port of an endoscope.
8. We do not think the name BioShield will cause any confusion in the mind of the users of endoscopes and endoscope caps about the intended purpose of the BioShield.

Thank you,

A handwritten signature in black ink, appearing to read "Gulam Khan".

Gulam Khan
CEO
US Endoscopy

Cc: Andre Routh, PhD.
Dean Secrest

Tab 2 – Table of Contents

TABLE OF CONTENTS

US Endoscopy BioShield ERCP Biopsy Valve 510(k) Submission

| Section | Location | Check |
|---|--------------------|--------------|
| 510(k) Summary (if any) | Not supplied** | X |
| Indications for Use Statement | Inside Front Cover | √ |
| Cover Letter | Tab 1 | √ |
| TOC | Tab 2 | √ |
| Letter authorizing BSI to submit the 510(k) | Tab 3 | √ |
| Truthful and Accurate Statement | Tab 4 | √ |
| 510(k) Decision-Making Documentation | Tab 5 | √ |
| BSI review memorandum with supervisory sign off | Tab 6 | √ |
| Screening Checklist | Tab 7 | √ |

** Submitter provided a 510(k) Statement

Tab 3 – Authorization Letter

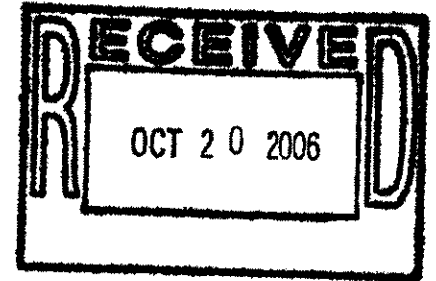


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fax 440/639-4495
customer service 800/769-8226
www.usendoscopy.com

18 October 2006

Via Fed Ex

Dr. Andre Routh
BSI Management Systems
12110 Sunset Hills Road, Suite 140
Reston, VA 20190



re: **510(k) Premarket Notification (Traditional)**

Dear Dr. Routh :

Enclosed please find two copies of a **510(k)** Premarket Notification submission, and a copy of the submission in electronic media on a CD. A copy of the CDRH Premarket Review Submission Cover Sheet, and 510(k) Screening Checklist are also included.

This letter authorizes British Standards Institute (BSI), in its capacity as an Accredited Person, to review the 510(k) pre-market notification that we have submitted for the BioShield® ERCP biopsy valve, to submit the 510(k) to FDA on our behalf, and to discuss its contents with FDA.

Please feel free to contact me with any questions. If I am unavailable for any reason, you may also contact either of my colleagues whose contact information is listed below.

With kindest regards,

R. Michael Wolf
Manager of Regulatory Affairs
mwolf@usendoscopy.com
800-769-8229 Ext. 378
440-639-4494 Ext. 378
216-308-2431 (mobile)

Establishment Registration Number 1528319

Additional contacts:

Mr. Dean Secrest – Executive Vice President – New Product Development – Ext. 311
Mr. Chris Kaye – Director of Engineering – Ext. 305

Tab 4 - Truthful and Accurate Statement

TRUTHFUL AND ACCURATE STATEMENT PREMARKET NOTIFICATION

[As required by 21 CFR 807.87(k)]

BSI Technical Reviewer's Statement

I certify that, in my capacity as a BSI Technical Reviewer, all data and information submitted in this premarket notification application are an accurate reflection of the data submitted to BSI by the submitter and that no material fact has been omitted.

BSI Technical Reviewer

Signature: Andre G Routh
Andre G. Routh, PhD, Senior Product Expert

Date: Feb 07, 2007
(Month/dd/yyyy)

Submitter's Statement

Truthful and Accurate Statement

I certify that, in my capacity as Manager of Regulatory Affairs for US Endoscopy Group, Inc., I believe to the best of my knowledge, that all data and information submitted in this pre-market notification are truthful and accurate and that no material fact has been omitted.

R. Michael Wolf

R. Michael Wolf

Date: 18 October 2007

510(k) number: New Submission

Tab 5 – SE Decision-Making Documentation

REVISED: 3/14/95

“SUBSTANTIAL EQUIVALENCE” (SE) DECISION-MAKING DOCUMENTATION”

K _____

Reviewer: Andre G. Routh, PhD (BSI Product Services, Healthcare)

Division/Branch: Third Party Review

Device Name: BioShield ERCP Biopsy Valve

Product to Which Compared (510(k) Number If Known):

- K010610 - Boston Scientific Rapid Exchange Biopsy Cap and Locking Device

| | Yes | No | |
|--|-----|----|---|
| 1. Is Product A Device | Yes | | If NO = Stop |
| 2. Is Device Subject To 510(k)? | Yes | | If NO = Stop |
| 3. Same Indication Statement? | | No | If YES = Go To 5 |
| 4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness? | | No | If YES = Stop NE |
| 5. Same Technological Characteristics? | Yes | | If YES = Go To 7 |
| 6. Could The New Characteristics Affect Safety Or Effectiveness? | | No | If YES = Go To 8 |
| 7. Descriptive Characteristics Precise Enough? | Yes | | If NO = Go To 10 If YES = Stop SE |
| 8. New Types Of Safety Or Effectiveness Questions? | | No | If YES = Stop NE |
| 9. Accepted Scientific Methods Exist? | Yes | | If NO = Stop NE |
| 10. Performance Data Available? | Yes | | If NO = Request Data |
| 11. Data Demonstrate Equivalence? | Yes | | Final Decision: |

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

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Tab 5 – SE Decision-Making Documentation

1. Intended Use:

US Endoscopy BioShield® - ERCP Biopsy Valve Indications for Use:

The single use BioShield® - ERCP biopsy valve is used to cover the opening to the biopsy/suction channel of Olympus and G5 and newer Fujinon gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.

Boston Scientific Rapid Exchange Biopsy Cap and Locking Device Indications for Use:

The Microvase Rapid Exchange Locking Device and Biopsy Cap System consists of accessories intended for use with Microvase Biliary Rapid Exchange devices.

The Microvase Rapid Exchange Locking Device is intended to lock the guidewire in place during ERCP procedures.

The Microvase Rapid Exchange Biopsy Cap is intended to facilitate the use of Rapid Exchange devices during ERCP procedures.

2. Device Description:

Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement.

- Is the device life-supporting or life sustaining? **NO**
- Is the device implanted (short-term or long-term)? **NO**
- Does the device design use software? **NO**
- Is the device sterile? **YES**
- Is the device for single use? **YES**
- Is the device over-the-counter or prescription use? **PRESCRIPTION**
- Does the device contain drug or biological product as a component? **NO**
- Is this device a kit? **NO**
- Provide a summary about the devices design, materials, physical properties and toxicology profile if important. **DESIGN IS VERY SIMILAR TO PREDICATES**

Please see Tab 6 Review Memorandum

Tab 5 – SE Decision-Making Documentation

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device: The BioShield is a device

2. Explain why not subject to 510(k): The BioShield is subject to 510(k)

3. How does the new indication differ from the predicate device's indication:

US Endoscopy BioShield® - ERCP Biopsy Valve Indications for Use:

The single use BioShield® - ERCP biopsy valve is used to cover the opening to the biopsy/suction channel of Olympus and G5 and newer Fujinon gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.

Boston Scientific Rapid Exchange Biopsy Cap and Locking Device Indications for Use:

The Microvvasive Rapid Exchange Locking Device and Biopsy Cap System consists of accessories intended for use with Microvvasive Biliary Rapid Exchange devices.

The Microvvasive Rapid Exchange Locking Device is intended to lock the guidewire in place during ERCP procedures.

The Microvvasive Rapid Exchange Biopsy Cap is intended to facilitate the use of Rapid Exchange devices during ERCP procedures.

4. Explain why there is or is not a new effect or safety or effectiveness issue:

The BioShield – ERCP Biopsy Valve has the following similarities with the predicate devices identified above:

1. The BioShield – ERCP biopsy valve and the predicate device have the same intended use. That is, they all are intended to cover the biopsy port in gastrointestinal endoscopes (also commonly called the biopsy channel, suction channel, or working channel of the scope) in order to seal off this channel to minimize leakage of insufflation and fluids during endoscopic procedures.
2. All of these devices allow for the passage of diagnostic and therapeutic devices into and out of the biopsy channel of the endoscope via slits or small openings in the body of the biopsy valve and/or in the lid or cap.
3. The BioShield – ERCP and the predicate devices are similar in design, employing mechanical seal features that minimize opportunities for leakage of air and fluids.
4. The BioShield – ERCP and the predicate devices are very similar in size and geometry, owing to the fact that they must attach securely to the same fixtures, i.e. the biopsy port of similarly designed endoscopes, and must allow for the passage of the same types of devices.
5. The BioShield – ERCP and the predicate devices are constructed of similar polymer materials. The BioShield – ERCP is constructed of a (b) (4) ; . The predicate devices are constructed of silicone rubber or other polymers which give them the combination of properties such as strength and elasticity that enable them to fulfill their intended use.
6. The BioShield – ERCP and the predicate devices are offered sterile.
7. The BioShield – ERCP and the predicate devices are for single patient use and are disposable.

Differences between the BioShield – ERCP and the predicate devices

1. The materials used in construction of the devices are not exactly the same, although they are all polymers with similar properties.
2. The external and internal geometry of the BioShield – ERCP are somewhat different from the predicate devices, owing to different approaches to the minimization of leakage under challenging procedural conditions.

Tab 5 – SE Decision-Making Documentation

3. The BioShield – ERCP does not currently employ any external features for locking of guidewires or other devices. The Microvasive Rapid Exchange Locking Device and Biopsy Cap System and the Wilson-Cook USW Cap and Wire Lock do include these features.
5. Describe the new technological characteristics: There are no new technological characteristics.
6. Explain how new characteristics could or could not affect safety or effectiveness: Safety and/or effectiveness not affected by new technological characteristics since there are none.
7. Explain how descriptive characteristics are not precise enough: Description is adequate for intended use.
8. Explain new types of safety or effectiveness questions raised or why the questions are not new: No new safety and effectiveness issues have emerged.
9. Explain why existing scientific methods can not be used: This biopsy valve is amenable to analysis with existing scientific methods.
10. Explain what performance data is needed: Adequate performance data has been presented by the submitter.
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent: The data demonstrate that the device is substantially equivalent to the predicate. A direct comparison with the predicate device was presented covering the areas important to the correct and safe use of the device.

ATTACH ADDITIONAL SUPPORTING INFORMATION

REVIEW MEMORANDUM FOR TRADITIONAL 510(k) SUBMISSIONS

Submission Information

510(k) Number: To be assigned

Submitter:

Mr. Michael Wolf,
United States Endoscopy Group,
5976 Heisley Road,
Mentor, OH 44060

Device Trade Name: BioShield – ERCP Biopsy Valve

Administrative Information

Truthful and Accuracy Certification: See Submission Section 4

510(k) Statement: See Submission Section 5

Indications for Use Statement: See Submission Section 4

Reason for the Submission

Traditional 510(k) for a new device

Device Classification

Device Class: II

Product Code: KOG

CFR Section: 21 CFR 876.1500

Device: Endoscope and/or accessories

Intended Use

US Endoscopy BioShield® - ERCP Biopsy Valve Indications for Use:

The single use BioShield® - ERCP biopsy valve is used to cover the opening to the biopsy/suction channel of Olympus and G5 and newer Fujinon gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.

Prescription Use.

Device Labeling: See Submission Section 9a

Device Instructions for Use: See Submission Section 9b

The Indications for Use Statement is consistent with the proposed labeling.

The submission contains labeling sufficient to describe the device, its intended use, and the directions for use per 21 CFR 807.87(e).

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Tab 6 – Review Memorandum Traditional 510(k)

Device Description

This device is a single use/disposable cap which is used to cover the biopsy/suction channel of endoscopes during ERCP (endoscopic retrograde cholangiopancreatography) and other endoscopic procedures. It provides access to the endoscope's working channel, minimizes leakage of biomaterial and other fluids during insufflation and instrument exchange, and allows for irrigation.

(b)(4)

A large rectangular area of the document is redacted with a solid grey fill. The redaction covers several lines of text, likely containing sensitive information.

The device weighs approximately 3.1 grams.

The device will be supplied sterile. Sterilization is accomplished using ethylene oxide (EtO).

Performance Characteristics

Submission Section 12 contains the performance testing that compared the BioShield against the predicate device (Boston Scientific Microvasive device). The tests fell into the following categories:

1. Device Exchange – insertion and extraction
2. Leakage during insufflation, device exchange and irrigation
3. Retention force of the biopsy valve to the endoscope

The tests demonstrated that the BioShield valve satisfies the safety and effectiveness requirements for an ERCP biopsy valve.

Comparison to Legally Marketed Devices

Submission Section 8 compares the BioShield against the predicate device (K010610 - Boston Scientific Microvasive Rapid Exchange Biopsy Cap and Locking Device).

US Endoscopy BioShield® - ERCP Biopsy Valve Indications for Use:

The single use BioShield® - ERCP biopsy valve is used to cover the opening to the biopsy/suction channel of Olympus and G5 and newer Fujinon gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.

Tab 6 – Review Memorandum Traditional 510(k)

**Boston Scientific Rapid Exchange Biopsy Cap and Locking Device
Indications for Use:**

The Microvasive Rapid Exchange Locking Device and Biopsy Cap System consists of accessories intended for use with Microvasive Biliary Rapid Exchange devices. The Microvasive Rapid Exchange Locking Device is intended to lock the guidewire in place during ERCP procedures. The Microvasive Rapid Exchange Biopsy Cap is intended to facilitate the use of Rapid Exchange devices during ERCP procedures.

**The BioShield – ERCP Biopsy Valve has the following similarities
with the predicate devices identified above:**

1. The BioShield – ERCP biopsy valve and the predicate devices have the same intended use. That is, they all are intended to cover the biopsy port in gastrointestinal endoscopes (also commonly called the biopsy channel, suction channel, or working channel of the scope) in order to seal off this channel to minimize leakage of insufflation and fluids during endoscopic procedures.
2. All of these devices allow for the passage of diagnostic and therapeutic devices into and out of the biopsy channel of the endoscope via slits or small openings in the body of the biopsy valve and/or in the lid or cap.
3. The BioShield – ERCP and the predicate devices are similar in design, employing mechanical seal features that minimize opportunities for leakage of air and fluids.
4. The BioShield – ERCP and the predicate devices are very similar in size and geometry, owing to the fact that they must attach securely to the same fixtures, i.e. the biopsy port of similarly designed endoscopes, and must allow for the passage of the same types of devices.
5. The BioShield – ERCP and the predicate devices are constructed of similar polymer materials. The BioShield – ERCP is constructed of a (b)(4) Test Data. The predicate devices are constructed of silicone rubber or other polymers which give them the combination of properties such as strength and elasticity that enable them to fulfill their intended use.
6. The BioShield – ERCP and the predicate devices are offered sterile.
7. The BioShield – ERCP and the predicate devices are for single patient use and are disposable.

Differences between the BioShield – ERCP and the predicate devices

1. The materials used in construction of the devices are not exactly the same, although they are all polymers with similar properties.
2. The external and internal geometry of the BioShield – ERCP are somewhat different from the predicate devices, owing to different

Tab 6 – Review Memorandum Traditional 510(k)

approaches to the minimization of leakage under challenging procedural conditions.

3. The BioShield – ERCP does not currently employ any external features for locking of guidewires or other devices. The Microvasive Rapid Exchange Locking Device and Biopsy Cap System and the Wilson-Cook USW Cap and Wire Lock do include these features.

Deficiencies and Resolution

A request for clarification about the name "BioShield" was made in response to a comment by the FDA Reviewer. The name was derived from "biopsy cap". No biological claims are implied or intended given that the ERCP valve is an accessory to an endoscope.

Reviewer's Analysis

| Submitter Supplied or Demonstrated: | Adequate Evidence? |
|---|----------------------------|
| Full description of the device | Yes |
| Consistent description of device and its intended use throughout the submission | Yes |
| Comparison of device with legally marketed devices | Yes |
| Identification of potentially significant differences | Yes |
| Appropriate test reports | Yes |
| Provision of sufficient information on test methods | Yes |
| Provision of test results sufficient to assess the differences | Yes |
| Addressed issues raised in relevant FDA guidance | No applicable FDA guidance |
| Correct application of standards | N/A for Traditional 510(k) |

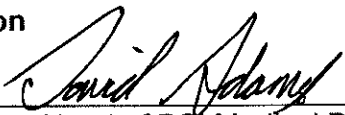
Tab 6 – Review Memorandum Traditional 510(k)

BSI RECOMMENDATION REGARDING SUBSTANTIAL EQUIVALENCE

The submitter's description of the particular design features and the comparative information between the subject device and predicate device demonstrate that the fundamental scientific technologies are the same.

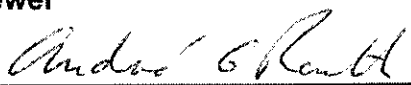
I recommend the device be determined substantially equivalent to the previously cleared device.

BSI Authorized Person

Signature: 
John Howlett, Head of BSI Medical Device Notified Body

Date: Feb 09, 2007
(Month/dd/yyyy)

BSI Technical Reviewer

Signature: 
Andre G. Routh, PhD, Senior Product Expert

Date: Feb 07, 2007
(Month/dd/yyyy)

Tab 7 – 510(k) Screening Checklist

510(k) SCREENING CHECKLIST

SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - **Do Sections 1 and 4**

Section 1: Required Elements for All Types of 510(k) submissions:

| | Present or Adequate | Missing or Inadequate |
|--|---------------------|-----------------------|
| Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510]] Manual. | Present | |
| Table of Contents. | Present | |
| Truthful and Accurate Statement. | Present | |
| Device's Trade Name, Device's Classification Name and Establishment Registration Number. | Present | |
| Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified). | Present | |
| Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510]] Manual. | Present | |
| Statement of Indications for Use that is on a separate page in the premarket submission. | Present | |
| Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510]] Manual. | Present | |
| 510(k) Summary or 510(k) Statement. | Statement | |
| Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals. | Present | |
| Identification of legally marketed predicate device. * | Present | |
| Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).] | Not required | |
| Class III Certification and Summary. ** | Not applicable | |
| Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)] | Not applicable | |
| 510(k) Kit Certification *** | Not applicable | |

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510]] Manual and the Convenience Kits Interim Regulatory Guidance.

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Tab 7 – 510(k) Screening Checklist

Sections 2 & 3 Not Required for Traditional 510(k)

Section 2: Required Elements for a SPECIAL 510(k) submission:

| | Present | Inadequate or Missing |
|---|---------|-----------------------|
| Name and 510(k) number of the submitter's own, unmodified predicate device. | | |
| A description of the modified device and a comparison to the sponsor's predicate device. | | |
| A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device. | | |
| Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device. | | |
| A Design Control Activities Summary that includes the following elements (a-c): | | |
| a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis. | | |
| b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied. | | |
| c. A Declaration of Conformity with design controls that includes the following statements: | | |
| A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities. | | |
| A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities. | | |

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

| | Present | Inadequate or Missing |
|--|---------|-----------------------|
| For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.) | | |
| For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.] | | |
| For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device. | | |
| For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device. | | |
| For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence. | | |
| Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence. | | |

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Tab 7 – 510(k) Screening Checklist

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

| | Present | Inadequate or Missing |
|--|----------------------|-----------------------|
| a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation: | Present | |
| b) Sterilization and expiration dating information: | Present | |
| i) Sterilization process | Traditional ETO | |
| ii) Validation method of sterilization process | Present | |
| iii) SAL | 10 ⁻⁶ SAL | |
| iv) Packaging | Present | |
| v) Specify pyrogen free | Not applicable | |
| vi) ETO residues | Defined | |
| vii) Radiation dose | Not applicable | |
| viii) Traditional Method or Non-Traditional Method | Traditional ETO | |
| c) Software Documentation: | Not applicable | |

Items with checks in the "Present or Adequate" column do not require additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening Yes No

BSI Technical Reviewer: Andre G. Routh
 Andre G. Routh, PhD, BSI Senior Product Expert

Date: Feb 07, 2007
 (Month/dd/yyyy)

Concurrence by Review Branch: _____

Date: _____

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 for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

Uploaded on March 3, 2004

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THIRD PARTY

From: Reviewer(s) - Name(s) 3rd Party - BSI

Subject: 510(k) Number K070420

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Section 522 Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

- Truthful and Accurate Statement Requested Enclosed
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

- Animal Tissue Source YES NO
- Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

K07 CLASS II 976.1500

Review: [Signature] ULDB 3/12/07
(Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 3/19
(Division Director) (Date)

THIRD PARTY

THIRD PARTY REVIEW CHECKLIST

| | | |
|--|--------------------------------------|-------------------------------------|
| 1. Is this 510(k) eligible for third party review, i.e.: | | |
| a. Is the device on the list of eligible devices?* | <input checked="" type="radio"/> Yes | <input type="radio"/> No |
| b. Can a determination of substantial equivalence be made without clinical data? | <input checked="" type="radio"/> Yes | <input type="radio"/> No |
| c. Are you aware of the 510(k) holder being the subject of an Integrity Investigation? | <input type="radio"/> Yes | <input checked="" type="radio"/> No |

IF THE ANSWER IS "NO" TO A or B above, or "YES" to C above, PLEASE BRING THE SUBMISSION TO POS IMMEDIATELY.

Are the following elements included in the submission:

| | | |
|---|--------------------------------------|--------------------------|
| 2. A cover letter signed by the third party's official correspondent clearly identifying: | | |
| a. The purpose of the submission | <input checked="" type="radio"/> Yes | <input type="radio"/> No |
| b. The name and address of the third party | <input checked="" type="radio"/> Yes | <input type="radio"/> No |
| c. The name and address of the 510(k) holder | <input checked="" type="radio"/> Yes | <input type="radio"/> No |
| d. The name of the device (trade name, common or usual name, and FDA classification name) | <input checked="" type="radio"/> Yes | <input type="radio"/> No |
| e. The third party's recommendation with respect to the substantial equivalence of the device | <input checked="" type="radio"/> Yes | <input type="radio"/> No |
| f. The date the third party first received the 510(k) from the 510(k) holder | <input checked="" type="radio"/> Yes | <input type="radio"/> No |

| | | |
|--|--------------------------------------|--------------------------|
| 3. A letter signed by the 510(k) holder authorizing the third party to submit the 510(k) on its behalf and to discuss its contents with FDA. | <input checked="" type="radio"/> Yes | <input type="radio"/> No |
|--|--------------------------------------|--------------------------|

| | | |
|---|--------------------------------------|--------------------------|
| 4. The complete 510(k) conforming to FDA's established requirements relating to content and form of such submissions. | <input checked="" type="radio"/> Yes | <input type="radio"/> No |
|---|--------------------------------------|--------------------------|

| | | |
|---|-----|----|
| 5. A complete review of the 510(k), signed by all personnel who conducted the third party review and by an individual within the third party responsible for supervising third party reviews, with a recommendation concerning the substantial equivalence of the device. | Yes | No |
|---|-----|----|

Page 2 - Third Party Review Checklist

| | | |
|---|--------------------------------------|--------------------------|
| 6. A certification that: | | |
| a. The third party continues to meet the personnel qualifications and prevention of conflict of interest criteria reviewed by FDA | <input checked="" type="radio"/> Yes | <input type="radio"/> No |
| b. Statements made in the third party's review are true and accurate to the best knowledge of the third party | <input checked="" type="radio"/> Yes | <input type="radio"/> No |
| c. The third party's review is based on the 510(k) that it is submitting with the review | <input checked="" type="radio"/> Yes | <input type="radio"/> No |
| d. The third party understands that the submission to the government of false information is prohibited | <input checked="" type="radio"/> Yes | <input type="radio"/> No |

| | | |
|---|--------------------------------------|--------------------------|
| 7. Are the following forms included in the submission as discussed in the Center's guidance document entitled Third Party Review-An Instruction Manual for Conducting Reviews of Premarket Notifications: | | |
| a. Third Party Premarket Notification (510(k)) Checklist for Acceptance Decision (Parts I and II) | <input checked="" type="radio"/> Yes | <input type="radio"/> No |
| b. Record of Deficiencies, if applicable (attachment 1a) | <input checked="" type="radio"/> Yes | <input type="radio"/> No |
| c. Indications for Use Form | <input checked="" type="radio"/> Yes | <input type="radio"/> No |
| d. 510(k) Summary or Statement (attachment 1c) | <input checked="" type="radio"/> Yes | <input type="radio"/> No |
| e. 510(k) Truthful and Accurate Statement (attachment 1d) | <input checked="" type="radio"/> Yes | <input type="radio"/> No |
| f. Third Party "Substantial Equivalence" (SE) Decision Making Documentation (attachment 2) | <input checked="" type="radio"/> Yes | <input type="radio"/> No |

IF ANY OF THE ABOVE INFORMATION IS NOT INCLUDED WITH THE THIRD PARTY'S SUBMISSION OR IS NOT ADEQUATE, CONTACT THE THIRD PARTY AND ATTEMPT TO RESOLVE THE DEFICIENCY. PLEASE INCLUDE A MEMORANDUM TO THE RECORD OF THE TELEPHONE CALL. WHEN THE INFORMATION IS RECEIVED PLEASE REVISE THIS CHECKLIST OR COMPLETE A NEW ONE.

COMMENTS: _____

*If the third party incorrectly classified the device and it is not a device type eligible for third party review please bring to POS.

Morris, Janine M.

From: Andre Routh [Andre.Routh@bsi-global.com]
Sent: Tuesday, March 13, 2007 11:39 PM
To: Morris, Janine M.
Cc: Rechen, Eric J.
Subject: RE: K070420 US Endoscopy
Attachments: K070420 Tab 5 Substantial Equivalence Decision Making Document US Endo ERCP Biopsy Valve Rev 2.doc; K070420 Tab 6 Review Memorandum Addendum.doc

Janine,

Thank you for that very helpful analysis of the submission. I must apologize for the confusion over which documents came from US Endoscopy and which documents were the review by BSI. The concept was that the client's 510(k) documents would be divided into Sections while the BSI review would be divided into Tabs. While the two sets of documents were separated in different sets of labeled folders, it seemed as if it would be readily evident which was which. We didn't take into account the fact that the documents might be consolidated into the same folder. We will try to develop a system that avoids such confusion in the future.

With regard to your comments on the SE documentation chart in Tab 5: you are quite correct, there was a logic failure. Please see the attached revision to Tab 5, which has been substantially reworked and is, hopefully, now correct.

Please see the addendum to Tab 6 which summarizes the performance characteristics, biocompatibility data, sterilization method, and provides a recommendation on substantial equivalence.

Should I send printed versions of the attachments to the DMC or are the electronic copies sufficient?

Best Regards,

Andre Routh

3/14/2007

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

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REVISED: 3/14/95

**“SUBSTANTIAL EQUIVALENCE” (SE) DECISION-MAKING
 DOCUMENTATION”**
 K070420

Reviewer: Andre G. Routh, PhD (BSI Product Services, Healthcare)

Division/Branch: Third Party Review

Device Name: BioShield ERCP Biopsy Valve

Product to Which Compared (510(k) Number If Known):

- K010610 - Boston Scientific Rapid Exchange Biopsy Cap and Locking Device

| | Yes | No | |
|--|-----|----|---|
| 1. Is Product A Device | Yes | | If NO = Stop |
| 2. Is Device Subject To 510(k)? | Yes | | If NO = Stop |
| 3. Same Indication Statement? | | No | If YES = Go To 5 |
| 4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness? | | No | If YES = Stop NE |
| 5. Same Technological Characteristics? | | No | If YES = Go To 7 |
| 6. Could The New Characteristics Affect Safety Or Effectiveness? | | No | If YES = Go To 8 |
| 7. Descriptive Characteristics Precise Enough? | Yes | | If NO = Go To 10 If YES = Stop SE |
| 8. New Types Of Safety Or Effectiveness Questions? | | | If YES = Stop NE |
| 9. Accepted Scientific Methods Exist? | | | If NO = Stop NE |
| 10. Performance Data Available? | | | If NO = Request Data |
| 11. Data Demonstrate Equivalence? | | | Final Decision: |

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:

US Endoscopy BioShield® - ERCP Biopsy Valve Indications for Use:

The single use BioShield® - ERCP biopsy valve is used to cover the opening to the biopsy/suction channel of Olympus and G5 and newer Fujinon gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.

Boston Scientific Rapid Exchange Biopsy Cap and Locking Device Indications for Use:

The Microvasive Rapid Exchange Locking Device and Biopsy Cap System consists of accessories intended for use with Microvasive Biliary Rapid Exchange devices.

The Microvasive Rapid Exchange Locking Device is intended to lock the guidewire in place during ERCP procedures.

The Microvasive Rapid Exchange Biopsy Cap is intended to facilitate the use of Rapid Exchange devices during ERCP procedures.

2. Device Description:

Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement.

- Is the device life-supporting or life sustaining? **NO**
- Is the device implanted (short-term or long-term)? **NO**
- Does the device design use software? **NO**
- Is the device sterile? **YES**
- Is the device for single use? **YES**
- Is the device over-the-counter or prescription use? **PRESCRIPTION**
- Does the device contain drug or biological product as a component? **NO**
- Is this device a kit? **NO**
- Provide a summary about the devices design, materials, physical properties and toxicology profile if important. **DESIGN IS VERY SIMILAR TO PREDICATES**

Please see Tab 6 Review Memorandum

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

3. How does the new indication differ from the predicate device's indication:

The wording of the Indications for Use statements for the proposed device and the predicate are different:

- The first sentence of both indications statements are different, defining the range of endoscopes and/or accessories with which the devices are intended to be used.
- The proposed device does not have a locking device for guidewires.
- The description of the accessory devices is different. However, the same types of device will be used with both.

4. Explain why there is or is not a new effect or safety or effectiveness issue:

With the exception of the fact that the proposed device does not have a guidewire locking feature, the two devices are functionally and mechanically very similar:

- Both devices cap the biopsy port to minimize fluid leakage during endoscopic procedures.
- Both devices allow for the passage of diagnostic and therapeutic devices into and out of the biopsy channel of the endoscope
- Both devices are similar in design, size and geometry
- Both are single use, sterile devices.

Any detail differences will not create unanticipated effects that affect safety or effectiveness.

5. Describe the new technological characteristics:

The BioShield – ERCP valve is constructed of (b) (4); (approved for use in applications that require United States Pharmacopoeia (USP) XIX class VI certification).

6. Explain how new characteristics could or could not affect safety or effectiveness:

The valve is made from (b) (4); that has been used successfully in similar approved valves and other medical devices and does not pose a safety issue. Predicate devices are made from silicone rubber or other polymers which give them similar strength and elasticity that enables them to fulfill their intended purpose.

The test report (Submission Section 12) demonstrates that the valve is suitable for its intended purpose.

ATTACH ADDITIONAL SUPPORTING INFORMATION

Performance Characteristics

Submission Section 12 contains the performance testing that compares the BioShield to the predicate device (Boston Scientific Microvasive device).

The device is relatively simple. It is pushed onto the accessory port of an endoscope and is retained in position by friction and the elastic properties of the device. The device has (b) (4)

. The slit allows for the insertion and withdrawal of catheters through the device into the lumen of the endoscope.

From a performance perspective, the device should seal the port when required, allow for device insertion and exchange, prevent leakage from or into the port, and remain in position while required. US Endoscopy performed a series of functional tests that demonstrated that the device satisfied these requirements. The tests fell into the following categories:

1. Device Exchange – insertion and extraction
2. Leakage during insufflation, device exchange and irrigation
3. Retention force of the biopsy valve to the endoscope

The tests demonstrated that the BioShield valve was functionally equivalent to the predicate and satisfies the functional and safety requirements for an ERCP biopsy valve.

Device Biocompatibility

Section 11 of the Submission includes a biocompatibility review. Under normal conditions of use, the device will not contact the patient. The caregivers will be gloved.

The main two components of the device are made from (b) (4) with an FDA-approved (b)(4) (b)(4) adhesive is used to bond the insert in place in the outer component. Isopropyl alcohol is used for cleaning.

Biocompatibility testing was performed by NAMSA (Northwood, OH). Section 11 of the Submission contains four NAMSA Biocompatibility Test Reports:

- Cytotoxicity Study Using the ISO Elution Method (1X MEM Extract) (NAMSA 06T_45733_01)
 - No evidence of cell lysis or toxicity
- ISO Intracutaneous Study – Extract (NAMSA 06T_45733_02, 06T_45733_03)

- The Primary Irritation Index characterization for the extracts was negligible using sodium chloride (SC) and sesame oil (SO) extracts injected intracutaneously in rabbits.
- USP and ISO Systemic Toxicity Study – Extract (NAMSA 06T_45733_04, 06T_45733_05)
 - No mortality or evidence of toxicity from injections of SC or SO extract in mice.
- USP Physicochemical Testing – Plastics – Complete (NAMSA 06T_45733_06)
 - Non-volatile residue, residue on ignition, heavy metals and buffering capacity were within limits after extraction with USP purified water.

The conclusion is that the materials are biocompatible. Any conceivable biocompatibility risk is mitigated further by the fact that the valve will not make contact with the patient.


Sterilization Information

Section 10 of the submission contains a synopsis of the sterilization method.

The devices will be ETO sterilized at contract sterilizer MMC/ETHOX:

(b) (4)



1. Description of the method used to validate the sterilization cycle:
The sterilization cycle will be validated using the AAMI overkill method.
2. Description of the packaging to maintain the device's sterility:
The biopsy valve is packaged in a TYVEK/mylar pouch
3. (b) (4)

- 4.
5. Sterility Assurance Level:
The SAL is 10^{-6} using the AAMI overkill method

(b) (4)



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Summary of Substantial Equivalence Review

The review considered the following factors:

- **Intended use**
Both the proposed device and the predicate are elastomeric caps that fit onto the accessory (biopsy) port of endoscopes for use during ERCP procedures. Their function during the procedure is to either block the accessory port or to allow for the insertion of various catheters or tools into the accessory port.
- **Technological characteristics**
Both devices are very similar in design. The proposed device is made of a (b) (4). The predicate is made of biocompatible silicone rubber with very similar mechanical characteristics.

The predicate has a feature that allows for the locking of a guidewire during the procedure. The proposed device does not include such a feature.

Functional testing has demonstrated that these devices are functionally equivalent.

Based on the fact that both devices have the same intended use (endoscope accessory port caps for use during ERCP procedures) and the very similar technological characteristics, the reviewer recommends that the proposed device and the predicate device be found substantially equivalent.

Morris, Janine M.

From: Morris, Janine M.
Sent: Monday, March 12, 2007 7:58 AM
To: 'Andre Routh'
Cc: Rechen, Eric J.; Morris, Janine M.
Subject: RE: K070420 US Endoscopy

Andre,

I have completed reviewing the 510k you submitted on behalf of US Endoscopy. For the most part it appears complete. However, there are a few errors in the SE documentation that need correction.

Under Tab 5 the SE documentation chart is not right. The reviewer answered all the questions and therefore was not following the instructions. Also the answer to question 5 (same technological characteristics?) is technically "no" since the memo indicates there are differences. I would prefer these differences to be described and an explanation as to why the differences are not significant. Please carefully review the chart and have it revised accordingly.

On page 3 of this section where the reviewer is to answer the appropriate questions, i.e., all "no" responses and any "yes" responses to 4, 6, 8, and 11, there needs to be some revision. This is where the reviewer provides his/her analysis of the data provided by the firm:

#3-the reviewer repeats the indication for use for the device and predicate. Although it is obvious the differences it is preferred that some conclusion or explanation is provided about the differences.

#4-this should only be an explanation of why the differences in the indication do not alter the intended therapeutic effect. The reviewer provided a listing of the similarities and differences of the entire devices.

#5-as explained above this is where an explanation of the differences should be described.

#6-if there are no new characteristics then this is not to be explained but if there are differences then a description is provided as to whether these differences could potentially impact safety and effectiveness and why or why not. If they could impact S&E then you go to #8 and explain why they do not raise a new type of question then proceed to #9 and explain what testing was done to demonstrate SE.

If they don't impact S&E then you go to #7 and explain what information was provided to describe the characteristics that demonstrate SE.

A couple of other points about the memo under Tab 6, under performance characteristics the reviewer should elaborate about the performance testing and why they believe this testing is adequate? Also, there is no discussion of the biocompatibility (should describe at a minimum what testing was performed or if none why that is acceptable) or sterilization/packaging (should describe at a minimum the 5 elements of sterilization review). The review memo should summarize what was reviewed and needed to make an SE decision.

3/12/2007

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

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Finally, it was confusing to figure out what was from BSI and what was from US Endoscopy. Things are not labeled sufficiently. It is best to present the BSI review and analysis in the front of the submission with all the administrative requirements and then provide a clear division of what US Endoscopy submitted to BSI. This is a recommendation for any future submission and is not necessary to complete this review.

If you provide me with a revised memo and SE documentation by the end of the week I will not place this on hold. If you believe it will take longer than a couple of days then let me know and I will place the file on hold until a complete response is received by DMC.

Thank you and contact me if you have any questions about submission.

Janine M. Morris

Chief, Urology and Lithotripsy Devices Branch (ULDB)
Division of Abdominal, Reproductive and Radiological Devices (DRARD)
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From: Andre Routh [mailto:Andre.Routh@bsi-global.com]
Sent: Wednesday, February 21, 2007 11:21 AM
To: Garcia, Diane; Shulman, Marjorie G.
Cc: Morris, Janine M.; Obst, John*; Stuart, Julie (Brandi)
Subject: RE: K070420 US Endoscopy

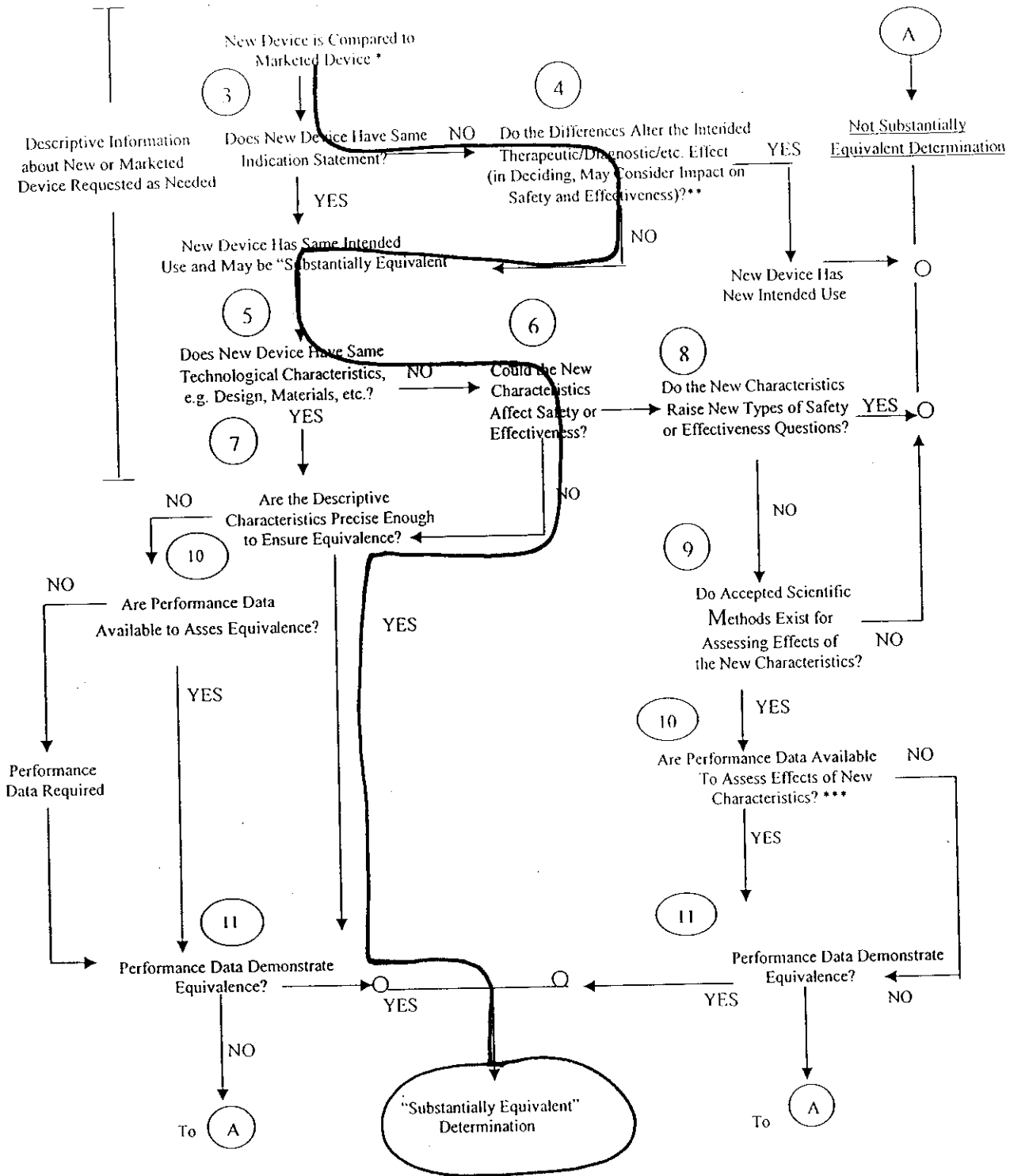
Hi Diane,

The US Endoscopy information that they submitted to us is divided into **SECTIONS**.

The review that we did, as Third-Party Reviewers, is divided into **TABS**.

Section 1 of the US Endoscopy submission is the CDRH Premarket Review Submission Cover Sheet that identifies the review as being a "510(k), Traditional, Third Party".

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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