



Food and Drug Administration
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December 21, 2015

CooperSurgical, Inc.
Roaida Johnson
Associate Director, New Product Development
95 Corporate Drive
Trumbull, CT 06611

Re: K153092
Trade/Device Name: Ally Uterine Positioning System™
Regulation Number: N/A
Regulation Name: N/A
Regulatory Class: Not Classified
Product Code: LKF
Dated: December 8, 2015
Received: December 9, 2015

Dear Roaida Johnson,

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

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153092

Device Name

Ally Uterine Positioning System™

Indications for Use (Describe)

Ally Uterine Positioning System™

The Ally Uterine Positioning System™ (UPS) is intended to assist the surgical staff in mounting, positioning and holding uterine manipulators during gynecological laparoscopic surgical procedures. It is intended for use by trained operating room personnel in an operating room environment.

Adapter Drape for the Ally UPS System

The Advincula Delineator™ Adapter Drape for the Ally Uterine Positioning System™ UPS is intended to assist the surgical staff in mounting, positioning, and holding uterine manipulators during gynecological laparoscopic surgical procedures. It is intended for use by trained operating room personnel in an operating room environment.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
CooperSurgical Ally Uterine Positioning System™ (UPS)
K153092

Submitter Information

Company Name: CooperSurgical Inc.

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Fax: 203-601-9870

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Associate Director of New Product Development

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roaida.johnson@coopersurgical.com

Date Prepared: December 15, 2015

Device Information:

Trade Name: Ally Uterine Positioning System™
Common Name: Holder, Manipulator, Positioner, Arm
Classification: Unclassified
Classification Name: Unclassified
Product Code: LKF

Predicate Device Information:

The CooperSurgical Ally Uterine Positioning System™ is substantially equivalent to the predicate CooperSurgical Ally Uterine Positioning System™ (K141523)

Device Description:

The CooperSurgical Ally Uterine Positioning System™ (UPS) consists of a single, multi- segmented, articulating arm that attaches to a standard operating room bed rail, and a separate, sterile, disposable Ally UPS Adapter Drape that is used to attach a uterine manipulator to the Ally UPS. When unlocked, the articulation of the arm allows the attached manipulator to be positioned by the user. The segmented design of the arm allows lateral/medial movement from a single point to position the uterine manipulator. The arm is then locked in the desired position by releasing a foot pedal, activating a linear actuator that applies tension to an internal cable, drawing the segments together and thus locking the arm.

The Ally UPS is not intended for patient contact. The Adapter Drape for the Ally UPS is single- use and sterilized by ethylene oxide. The Ally UPS Adapter Drape secures either the Cooper Surgical RUMI II

Uterine Manipulator Handle, or the Advincula Arch Uterine Manipulator Handle, to the distal end of the Ally UPS arm. The purpose of this submission is to gain clearance to add the new Advincula Delineator™ Adapter Drape to the system, which allows the Ally UPS to be used with the CooperSurgical Advincula Delineator™ Uterine Manipulator.

Indications for Use:

Ally Uterine Positioning System™ (UPS)

The Ally Uterine Positioning System™ (UPS) is intended to assist the surgical staff in mounting, positioning and holding uterine manipulators during gynecological laparoscopic surgical procedures. It is intended for use by trained operating room personnel in an operating room environment.

Adapter Drape for the Ally UPS System

The Advincula Delineator™ Adapter Drape for the Ally Uterine Positioning System™ UPS is intended to assist the surgical staff in mounting, positioning, and holding uterine manipulators during gynecological laparoscopic surgical procedures. It is intended for use by trained operating room personnel in an operating room environment.

Substantial Equivalence Analysis

Attribute	Subject Ally Uterine Positioning System™	Predicate Ally Uterine Positioning System - K141523
Indications for Use: Ally UPS	The Ally UPS is intended to assist the surgical staff in mounting, positioning, and holding uterine manipulators during gynecological laparoscopic surgical procedures. It is intended for use by trained operating room personnel in an operating room environment.	Same
Indications for Use: Adapter Drape	The Advincula Delineator™ Adapter Drape for the Ally UPS System is intended to assist the surgical staff in mounting, positioning, and holding uterine manipulators during gynecological laparoscopic surgical procedures. It is intended for use by trained operating room personnel and in an operating room environment.	Same
Patient Contact Type	Non-Patient Contacting	Same
Ally UPS Material	Stainless steel, aluminum	Same
Adapter Drape Material	Lexan, 2 mil polyethylene film	Same
Packaging	Tyvek 1073B/polyester/polyethylene heat sealed chevron pouch. The pouches are packaged in SBS paperboard cartons and are placed into corrugated shipping cases for transport and storage.	Same
Sterilization	The Delineator Adapter Drape is sterilized by ethylene oxide to a Sterility Assurance Level (SAL) of 10 ⁻⁶ .	Same

The substantial equivalence of the subject Ally UPS System with the Advincula Delineator™ Adapter Drape to the predicate is shown by similarity of intended use, indications for use, materials, design, function, sterilization, and performance.

Non-Clinical Performance Testing

The modified Ally UPS with the Advincula Delineator™ Adapter Drape was compared to the predicate for the following performance characteristics:

- Adapter Pull-off Force
- Drape Pull-off Force
- Handle Push Force

The Advincula Delineator™ Adapter Drape maintained its specifications for the duration of its shelf life as demonstrated by stability testing in accordance with ASTM F1980-07.

Sterilization validation performed per ISO 11135-1:2007– Sterilization of healthcare products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices, and ISO 11135-2:2008 – Sterilization of health care products – Ethylene oxide – Part 2: Guidance on the application of ISO 11135-1 demonstrated that the Advincula Delineator™ Adapter Drape meets the appropriate ethylene oxide and ethylene chlorohydrin residual levels per the requirements of ANSI/AAMI/ISO 10993-7:2008(R)2012 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals.

The Ally UPS is in compliance with the following standards:

- IEC 60601-1 CORR 1 & 2 2007 – Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2 – Medical Electrical Equipment – Part 1-2: General Requirements for Safety

Clinical Performance Testing

Clinical testing was not required to support the conclusion of substantial equivalence.

Conclusion

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicate, the modified Ally Uterine Positioning System™ (UPS) has been shown to be substantially equivalent to the predicate device identified, and does not present any new issues of safety or effectiveness.