March 14, 2018

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

Re: K180429
Trade/Device Name: Advincula Delineator™ Uterine Manipulator
Regulation Number: 21 CFR§ 884.1640
Regulation Name: Culdoscope and Accessories
Regulatory Class: II
Product Code: HEW
Dated: February 14, 2018
Received: February 16, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Charles Viviano -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180429

Device Name
Advincula Delineator™ Uterine Manipulator

Indications for Use *(Describe)*
The CooperSurgical Advincula Delineator Uterine Manipulator is indicated to provide delineation of the vaginal fornices and maintain pneumoperitoneum as a uterine manipulator during Total Laparoscopic Hysterectomy (TLH), Laparoscopic Assisted Vaginal Hysterectomy (LAVH) and/or Laparoscopic Supracervical Hysterectomy (LSH).

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.

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

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K180429
Advincula Delineator™
Uterine Manipulator
Special 510(k) Summary

Submitter Information

Company Name: CooperSurgical Inc.

Company Address: 95 Corporate Drive
Trumbull, CT 06611
Telephone: 203-601-5200 Ext. 3325
Fax: 203-601-9870

Contact Person: Roaida Johnson

Date Prepared: March 13, 2018

Device Information

Trade Names:	Advincula Delineator™ Uterine Manipulator
Common Name:	Uterine Manipulator
Classification:	Class II per 21 CFR 884.1640
Classification Name:	Culdoscope and Accessories
Product Code:	HEW – Culdoscope (And Accessories)

Predicate Device Information

The Advincula Delineator uterine manipulator is substantially equivalent to the following predicates:

Predicate: CooperSurgical Advincula Delineator Uterine Manipulator (K143650)

The predicate device has not been subject to a design-related recall.

Device Description

The Advincula Delineator is a uterine manipulator that is intended for use during total laparoscopic hysterectomy (TLH), laparoscopic assisted vaginal hysterectomy (LAVH), and/or laparoscopic supracervical hysterectomy (LSH) procedures. It is single-use, disposable, and provided sterile. The device has a distal balloon built into the arched shaft, and a sliding colpotomy cup, called a Koh-Cup, that locks into place with a position lock. The handle at the proximal end allows the user to hold the device and to manipulate the uterus. When properly positioned, the outer rim of the Koh-Cup delineates the vaginal fornices and provides an anatomical landmark to facilitate uterine resection. An occluder balloon is used to maintain pneumoperitoneum during the procedure.

The Advincula Delineator is available with Koh-Cups sized 2.5cm, 3.0cm, 3.5cm or 4.0cm in diameter. There are flexible plastic and Ultem plastic Koh-Cups available for use in electrocautery procedures, and a version with a stainless-steel outer rim for use in harmonic scalpel or laser procedures.

Indications for Use

The CooperSurgical Advincula Delineator Uterine Manipulator is indicated to provide delineation of the vaginal fornices and maintain pneumoperitoneum as a uterine manipulator during Total Laparoscopic Hysterectomy (TLH), Laparoscopic Assisted Vaginal Hysterectomy (LAVH) and/or Laparoscopic Supracervical Hysterectomy (LSH).

Substantial Equivalence Discussion

Table 1 provides a comparison of the subject and predicate device.

Table 1: Comparison of the Subject Advincula Delineator to the Predicate Devices

Attribute	**Subject Advincula Delineator**	**Predicate Advincula Delineator**
510(k) Number	K180429	K143650
Manufacturer	CooperSurgical	Same
Indications for Use	The CooperSurgical Advincula Delineator Uterine Manipulator is indicated to provide delineation of the vaginal fornices and maintain pneumoperitoneum as a uterine manipulator during Total Laparoscopic Hysterectomy (TLH), Laparoscopic Assisted Vaginal Hysterectomy (LAVH) and/or Laparoscopic Supracervical Hysterectomy (LSH).	Same
Fundamental Scientific Technology	The device has a distal balloon built into the arched shaft, and a sliding colpotomy cup, called a Koh-Cup, that locks into place. The handle at the proximal end allows the user to hold the device and manipulate the uterus, and the Koh-Cup delineates the vaginal fornices. An occluder balloon is used to maintain pneumoperitoneum.	Same
Manipulator Material(s)	Stainless steel, silicone, various plastics, adhesives and inks	Same
Koh-Cup Materials	Stainless steel, plastic (soft and hard)	Different; this device does not include a soft plastic cup
Vaginal Occlusion (pneumoperitoneum)	Occluder balloon with inflation capacity of 60-120cc	Same
Environment of use	Operating room	Same
Patient Contact	External communicating device, limited (≤24)	Same
Sterilization Method	Ethylene Oxide	Same
Number of Uses	Single-Use, Disposable	Same
Packaging	Individually packaged in a flexible blister pouch with a Tyvek lid, and three (3) pouches in an SBS box	Same
Shelf Life	1-Year	3-Years

The subject and predicate devices have the same indications for use and the same fundamental scientific technology. The only difference between the predicate and subject device is the material from which the

Koh-Cup component is made. This difference does not raise different questions of safety and effectiveness as compared to the predicate.

Non-Clinical Performance Testing

As part of demonstrating substantial equivalence to the predicate, the following tests were performed to evaluate the new Koh-cup for safety and performance:

- **Design Verification Testing**
  - Pull-Off Test: To verify that the modified Koh-Cup does not disassemble from the device when used as intended. The test results show that the subject Koh-Cup met the predetermined acceptance criterion.
  - Compression Test: To verify that the modified Koh-Cup can withstand adequate compression force. The test results show that the subject Koh-Cup met the predetermined acceptance criterion.

- **Design Validation Testing**
  - This test, which evaluated the use of the new Koh-Cup in a cadaveric model, validated that the Advincula Delineator with the modified Koh-Cup performs as intended and meets user needs.

- **Biocompatibility Testing per ISO 10993-1:2009**
  - Cytotoxicity per ISO 10993-5:2009; results demonstrated the new Koh-Cup was non-cytotoxic
  - Sensitization per ISO 10993-10:2010; results demonstrated the new Koh-Cup was non-sensitizing
  - Irritation per ISO 10993-10:2010; results demonstrated the new Koh-Cup was non-irritating

- **Shelf Life Testing per ASTM F1980-07 (Reapproved 2011)**
  - Design verification testing was performed after 1 year of accelerated aging. Devices met predetermined acceptance criteria.

Conclusion

The Advincula Delineator Uterine Manipulator has the same intended use as the predicate device. The addition of the new Koh-Cup material does not raise different questions of safety and effectiveness, and the results of the testing described above demonstrate that the subject device with the modified Koh-cup is as safe and effective as the predicate. Therefore, the subject device is substantially equivalent to the predicate.