May 21, 2020

CooperSurgical, Inc.
Kyle Hooper
Regulatory Affairs Associate
95 Corporate Drive
Trumbull, CT 06611

Re: K201086
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: April 22, 2020
Received: April 23, 2020

Dear Kyle Hooper:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Jason R. Roberts, Ph.D.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K201086

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, Laparoscopic Assisted Vaginal Hysterectomy and/or Laparoscopic Supra-Cervical Hysterectomy.

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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# 510(k) SUMMARY

**510(K) SUBMITTER**

Company Name: CooperSurgical Inc.
Company Address: 95 Corporate Drive
Trumbull, CT 06611

**CONTACT**

Name: Kyle Hooper
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Email: Kyle.Hooper@coopersurgical.com

Date Prepared: May 20, 2020

**DEVICE IDENTIFICATION**

Trade Name: Advincula Delineator™ Uterine Manipulator
Common Name: Uterine Manipulator
Regulation Number: 21 CFR 884.1640
Regulation Name: Culdoscope and Accessories
Regulatory Class: Class II
Product Code: HEW
Product Code Name: Culdoscope (and Accessories)

**PREDICATE DEVICE INFORMATION**

Advincula Delineator™ Uterine Manipulator (K180429).

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

**DEVICE DESCRIPTION**

The Advincula Delineator Uterine Manipulator 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 Uterine Manipulator is available with Koh-Cups sized 2.5cm, 3.0cm, 3.5cm or 4.0cm in diameter. The Koh-Cup is made of Hytrel and the manipulator is made of stainless steel, silicone, various plastics, adhesives and inks. The subject device is intended to be used in hospitals.

**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, Laparoscopic Assisted Vaginal Hysterectomy and/or Laparoscopic Supra-Cervical Hysterectomy.

**SUBSTANTIAL EQUIVALENCE DISCUSSION**

**Table 1: Subject and Predicate Device Comparison**

| **Attribute** | **Subject** Advincula Delineator™ Uterine Manipulator | **Predicate** (K180429) Advincula Delineator™ Uterine Manipulator | **Discussion** |
|---|---|---|---|
| **Manufacturer** | CooperSurgical, Inc. | CooperSurgical, Inc. | |
| **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, Laparoscopic Assisted Vaginal Hysterectomy and/or Laparoscopic Supra-Cervical Hysterectomy. | 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. | 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 | Stainless steel, silicone, various plastics, adhesives and inks | **Same** |
| **Koh-Cup Materials** | Hytrel | Isothane | **Different** |
| **Vaginal Occlusion (Pneumoperitoneum)** | Occluder balloon with inflation capacity of 60-120cc | Occluder balloon with inflation capacity of 60-120cc | **Same** |
| **Environment of Use** | Operating Room | Operating Room | **Same** |

| | | | |
|---|---|---|---|
| **Patient Contact** | External communicating device, limited (<24) | External communicating device, limited (<24) | **Same** |
| **Sterilization Method** | Ethylene Oxide | Ethylene Oxide | **Same** |
| **Number of Uses** | Single-Use, Disposable | Single-Use, Disposable | **Same** |
| **Packaging** | Individually packaged in tray with Tyvek lid, and three (3) trays in an SBS box | Individually packaged in a flexible blister pouch with a Tyvek lid, and three (3) pouches in an SBS box | **Different** |
| **Shelf Life** | 1-year | 1-year | **Same** |

The subject and predicate devices have the same indications for use and the same fundamental scientific technology. The differences between the predicate and subject device is the material of the Koh-Cup component and packaging material. These differences do not raise different questions of safety and effectiveness as compared to the predicate.

**NON-CLINICAL PERFORMANCE**

As part of demonstrating substantial equivalence to the predicate, a risk analysis was completed to identify the risks associated with the Advincula Delineator™ Uterine Manipulator material changes. Verification testing were conducted to evaluate the modifications. The following tests associated with the device modifications were performed on the subject device according to methods and acceptance criteria outlined in the predicate device (K180429). The subject device passed all the testing in accordance with internal requirements and applicable standards to support substantial equivalence of the subject device.

- **Sterilization**
  - **ISO 10993-7:2008** Biological Evaluation of Medical devices – Part 7: Ethylene oxide sterilization residuals
  - **ISO 11135:2014** Sterilization of Health-care Product – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices

- **Shelf Life and Shipping**
  - Shelf life was demonstrated up to 1 year
  - **ISO 11607-1: 2006,** Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems, and Packaging Systems.
  - **ISTA 3A: 2008,** Packaged-Products for Parcel Delivery System Shipment 150 lb. or Less.
  - **ASTM F1980-16,** Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
  - Design verification testing was performed after accelerated aging equivalent to one year of real-time aging. Devices met predetermined acceptance criteria.

- **Design Verification Testing**
    - **Compression**: 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
    - **Pull Off:** 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.
    - **Distortion:** To verify that the modified Koh-Cup can withstand adequate force. The test results show that the subject Koh-Cup met the predetermined acceptance criterion
    - **Temperature Testing:** To verify that the modified Koh-Cup can withstand adequate temperature. The test results show that the subject Koh-Cup met the predetermined acceptance criterion.

- **Biocompatibility Testing** (Cytotoxicity, Sensitization, Irritation)
    - 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

**CONCLUSION**

The Advincula Delineator Uterine Manipulator has the same intended use as the predicate device. 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.