February 5, 2020

CooperSurgical, Inc.
Christine Kupchick
Regulatory Affairs Associate
95 Corporate Drive
Trumbull, CT 06611

Re: K200038
Trade/Device Name: Endosee System
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: Class II
Product Code: HIH, FAJ
Dated: January 7, 2020
Received: January 8, 2020

Dear Christine Kupchick:

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,

Jason 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)*
K200038

Device Name
Endosee System

Indications for Use *(Describe)*
The Endosee System is used to permit viewing of the adult cervical canal and uterine cavity for the purpose of performing diagnostic and therapeutic procedures. The types of procedures where the Endosee System could offer visualization include:

- Abnormal bleeding
- Infertility and pregnancy wastage
- Evaluation of abnormal hysterosalpingogram
- Intrauterine foreign body
- Amenorrhea
- Pelvic pain
- Directed biopsy
- Removal of fibroids and polyps
- Transection of intrauterine adhesions
- Transection of intrauterine septa

The Endosee System can also be used to permit viewing of the adult urinary bladder through a minimally invasive approach by utilizing natural orifices for the purpose of performing diagnostic and therapeutic procedures.

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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K200038

CooperSurgical
Healthy women, babies, and families™

510(k) SUMMARY

510(k) Submitter

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

Contact

Name: Christine Kupchick
Telephone: 203-601-5200 Ext. 3370
Fax: 203-601-9870
Email: christine.kupchick@coopersurgical.com

Date Prepared: January 07, 2020

Device Identification

Trade Name: Endosee® System
Common Name: Hysteroscope; Cystoscope
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and Accessories
Product Code: HIH; FAJ
Regulatory Class: Class II

Predicate Device Information

The subject Endosee System is substantially equivalent to the predicate Endosee System (K190639).

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

Device Description

The Endosee System is a handheld, battery-operated, portable endoscope that consists of a reusable Display Module with an LCD touchscreen monitor and a sterile, single-use cannula. It is intended for use in viewing the adult cervical canal, uterine cavity, or female urinary tract, including the bladder, during diagnostic or therapeutic hysteroscopy or cystoscopy procedures in an operating room, outpatient, or office setting. The Cannula has a light source and camera at the distal end, which are used for visualization and to capture image and video of the diagnostic area. The image and video signals are electronically transferred from the Cannula to the Display module via an electrical connector and cable, and the LCD monitor is used for viewing. The Endosee is provided with a Docking Station that recharges the battery in the Display Module and allows the user to download images/video from the internal device memory to an external computer.

INDICATIONS FOR USE

The Endosee System is used to permit viewing of the adult cervical canal and uterine cavity for the purpose of performing diagnostic and therapeutic procedures. The types of procedures where the Endosee System could offer visualization include:

- Abnormal bleeding
- Infertility and pregnancy wastage
- Evaluation of abnormal hysterosalpingogram
- Intrauterine foreign body
- Amenorrhea
- Pelvic pain
- Directed biopsy
- Removal of fibroids and polyps
- Transection of intrauterine adhesions
- Transection of intrauterine septa

The Endosee System can also be used to permit viewing of the adult urinary bladder through a minimally invasive approach by utilizing natural orifices for the purpose of performing diagnostic and therapeutic procedures.

SUBSTANTIAL EQUIVALENCE DISCUSSION

Table 1: Substantial Equivalence Comparison

Attribute	Subject Endosee System	Predicate Endosee System
Manufacturer	CooperSurgical, Inc.	CooperSurgical, Inc.
Indications for Use	The Endosee System is used to permit viewing of the adult cervical canal and uterine cavity for the purpose of performing diagnostic and therapeutic procedures. The types of procedures where the Endosee System could offer visualization include: abnormal bleeding, infertility and pregnancy wastage, evaluation of abnormal hysterosalpingogram, intrauterine foreign body, amenorrhea, pelvic pain, directed biopsy, removal of fibroids and polyps, transection of intrauterine adhesions, and transection of intrauterine septa. The Endosee System can also be used to permit viewing of the adult urinary bladder through a minimally invasive approach by utilizing natural orifices for the purpose of	The Endosee System is used to permit viewing of the adult cervical canal and uterine cavity for the purpose of performing diagnostic and therapeutic procedures. The types of procedures where the Endosee System could offer visualization include: abnormal bleeding, infertility and pregnancy wastage, evaluation of abnormal hysterosalpingogram, intrauterine foreign body, amenorrhea, pelvic pain, directed biopsy, removal of fibroids and polyps, transection of intrauterine adhesions, and transection of intrauterine septa. The Endosee System can also be used to permit viewing of the adult urinary bladder through a minimally invasive approach by utilizing natural orifices for the purpose of

	performing diagnostic and therapeutic procedures.	performing diagnostic and therapeutic procedures.
Fundamental Technology	Handheld, battery-operated endoscope that consists of a reusable, detachable Display Module and sterile, disposable Cannula with a handle; Wi-Fi capability.	Handheld, battery-operated endoscope that consists of a reusable, detachable Display Module and sterile, disposable Cannula with a handle; Wi-Fi capability.
Cannula Type and Dimensions	Type: Flexible Working Length: 276mm Largest Outer Diameter: 4.5mm	Type: Flexible Working Length: 276mm Largest Outer Diameter: 4.5mm
Cannula Working Channel	Working channel for fluid infusion and instrument access	Working channel for fluid infusion and instrument access
View	Field of View: 100° ± 5° Direction of View: 20° ± 3°	Field of View: 100° ± 5° Direction of View: 20° ± 3°
Light Source	LED	LED
Image Display	Handheld LCD display module	Handheld LCD display module
Cannula Patient-Contacting Materials	Direct: PEEK, ink, glass, adhesive, lens coating, surface black coating, Indirect: ABS, TPE, polycarbonate, adhesive, ink, silicone, PVC (non-phthalate), copper	Direct: PEEK, ink, glass, adhesive, lens coating, surface black coating, Indirect: ABS, TPE, polycarbonate, adhesive, ink, silicone, PVC, copper
Number of Uses	Cannula: single-use, disposable Display Module: reusable	Cannula: single-use, disposable Display Module: reusable
Cannula Sterilization	Ethylene oxide, SAL^{-6}	Ethylene oxide, SAL^{-6}

The subject and predicate devices have the same intended use.

The subject and predicate devices have the same fundamental technology, cannula type and dimensions, cannula working channel, field and direction of view, light source, image display, number of uses and sterilization. The subject Cannula differs from the predicate in indirect patient-contacting materials and an additional layer of shielding on the Cannula board. 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 Endosee Cannula material changes and additional shielding. 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 (K190639). The subject device passed all the testing in accordance with internal requirements and applicable standards to support substantial equivalence of the subject device.

- **Sterilization Evaluation per ISO 11135:2014**
  - Bioburden per ISO 11737-1:2018

- **Biocompatibility Testing per ISO 10993-1:2009**
  - Cytotoxicity per ISO 10993-5:2009
  - Irritation per ISO 10993-10:2010
  - Sensitization per ISO 10993-10:2010

- **Stability and Shelf Life of Cannula**
  The following tests were performed on samples accelerated aged to 6-months per ASTM F1980-16:
  - Leak Test

- **Performance Testing**
  - Fixed Pattern Noise Test

The following testing was leveraged from the predicate device (K190639). Test results from the predicate were used to support the subject device because the conditions were identical or the subject device modifications did not introduce a new worst-case configuration or scenario for testing.

- **Sterility Testing per ISO 11135-1:2014**
  - EO Residuals per ISO 10993-7:2008

- **Stability and Shelf Life of Cannula**
  The following tests were performed samples accelerated aged to 6-months per ASTM F1980-16:
  - Seal Tensile Strength
  - Seal Peel
  - Performance (Image Quality, Flow Rate, Leak, Bend, Tip Retention, Instrument Access)

- **Ship Testing per ISTA 3A:2008**
  - Bubble Leak per ASTM 2096-11

- **EMC and Electrical Safety**
  - UL Electrical Safety per ANSI/AAMI ES 60601-1:2005/(R)2012 and IEC 60601-2 18:2009 with Essential Performance per IEC 60601-2-18
  - UL EMC per IEC 60601-1-2:2014 and IEC 60601-2-18:2009 with Essential Performance per IEC 60601-2-18

- **Performance Testing**
  - Optical Distortion Test
  - Saline Flow Rate Test
  - 90° Bend Test
  - 3-Point Bend Test
  - LED Temperature Test

  - Drop Test per IEC 60601-1-15
  - IPX2 Ingress Test per IEC 60529:2004
  - System Level Verification

- **Software Verification per IEC 62304:2006 and as recommended in the FDA guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"**

- **Cybersecurity/Interoperability Information provided as recommended in FDA guidance, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices"**

- **Wireless information provided as recommended in FDA guidance, "Radio Frequency Wireless Technology in Medical Devices Guidance"**

- **Design Validation**

CONCLUSION

The results of the testing described above demonstrate that the subject Endosee System is as safe and effective as the predicate and supports a determination of substantial equivalence.