January 31, 2019

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

Re: K183020
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: October 31, 2018
Received: November 1, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Sharon M. Andrews -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)*
K183020

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 procedures. Generally recognized indications for diagnostic hysteroscopy include:

- Abnormal bleeding
- Infertility and pregnancy wastage
- Evaluation of abnormal hysterosalpingogram
- Intrauterine foreign body
- Amenorrhea
- Pelvic pain

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 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.

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

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510(k) Summary
K183020

Submitter Information

Company Name: CooperSurgical Inc.
Company Address: 95 Corporate Drive
Trumbull, CT 06611
Telephone: 203-601-5200
Fax: 203-601-9870

Contact Person: Roaida Johnson
Date Prepared: January 28, 2019

Device Information

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: II

Predicate Device Information

The subject Endosee System is substantially equivalent to the predicate Endosee Hysteroscope with Disposable Diagnostic (Dx) Cannula (K170660).

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, to perform diagnostic 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 procedures. Generally recognized indications for diagnostic hysteroscopy include:

- Abnormal bleeding
- Infertility and pregnancy wastage
- Evaluation of abnormal hysterosalpingogram
- Intrauterine foreign body
- Amenorrhea
- Pelvic pain

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 procedures.

Substantial Equivalence Discussion

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

Table 1: Subject and Predicate Device Comparison

Attribute	Subject Endosee System	Predicate Endosee Hysteroscope	Significant Differences
510(k) Number	Not yet assigned	K170660	N/A
Manufacturer	CooperSurgical, Inc.	CooperSurgical, Inc.	N/A
Indications for Use	The Endosee System is used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures. Generally recognized indications for diagnostic hysteroscopy include: Abnormal bleeding, Infertility and pregnancy wastage, Evaluation of	The Endosee Hysteroscope and Disposable Diagnostic (Dx) Cannula are used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures. Generally recognized indications for diagnostic hysteroscopy include: Abnormal bleeding, Infertility	Same

	abnormal hysterosalpingogram, Intrauterine foreign body, Amenorrhea, Pelvic Pain The Endosee System can also be used to permit viewing of the urinary bladder through a minimally invasive approach by utilizing natural orifices for the purpose of performing diagnostic procedures.	and pregnancy wastage, Evaluation of abnormal hysterosalpingogram, Intrauterine foreign body, Amenorrhea, Pelvic Pain The Endosee and Disposable Diagnostic (Dx) Cannula can also be used to permit viewing of the urinary bladder through a minimally invasive approach by utilizing natural orifices for the purpose of performing diagnostic procedures.	
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 Handheld Monitor and a sterile, disposable Cannula	Different. The subject device provides updated technology features and component configurations.
Cannula Type	Flexible	Flexible	Same
Patient Contacting Materials	PEEK, ink, glass, adhesive, lens coating, surface black coating	Glass, stainless steel, nylon, acrylic and adhesive	Different. The subject device contains PEEK, ink, and coatings.
Cannula Working Length	276mm	276mm	Same
Cannula Largest Outer Diameter	4.5mm	4.8mm	Different. The subject cannula largest outer diameter is smaller than that of the predicate.
Light Source	LED	LED	Same
Field of View	100° ± 5°	100° ± 5°	Same
Direction of View	20° ± 3°	20° ± 3°	Same
Image Display	Handheld LCD display module	Handheld LCD display module	Same
Cannula Sterilization	Ethylene oxide, SAL^{-6}	Ethylene oxide, SAL^{-6}	Same
Number of Uses	Cannula: single-use, disposable Display Module: reusable	Cannula: single-use, disposable Display Module: reusable	Same
Cannula Shelf-Life	6 months	3 years	Different. The subject device has a shorter

			shelf-life than the predicate.
Packaging	Cannula: Individually pouched or individually pouched with a pipette Display Module: Boxed with Docking Station, power cord, and USB cable	Cannula: Individually pouched or individually pouched with a pipette Display Module: Boxed with Docking Station, power cord, and USB cable	Same

The subject Endosee System has the same indications for use as the predicate device. Both devices have the same method of sterilization, number of uses, and patient contact duration. As described above, there are differences in materials and technology between the subject and predicate device. However, these differences do not raise different questions of safety or efficacy.

Non-Clinical Performance Testing
As part of demonstrating substantial equivalence to the predicate the following non- clinical tests were performed:

- **Sterility Testing per ISO 11135-1:2014**
  - EO Residuals per ISO 10993-7:2008
  - Bioburden per ISO 11737-1:2006 & 11737-2:2009
- **Biocompatibility Testing per ISO 10993-1:2009**
  - Cytotoxicity per ISO 10993-5:2009
  - Sensitization per ISO 10993-10:2010
  - Irritation per ISO 10993-10:2010
- **Shelf Life of Cannula**
  - Aged to 6-months per ASTM F1980-16
  - The following tests were performed on 6-month accelerated aged samples:
    - Seal Tensile Strength
    - Seal Peel
    - Functional (Image Quality, Flow Rate, Leak, Bend)
- Ship Testing per ISTA 3A:2008
  - Bubble Leak per ASTM 2096-11
- **Functional Testing**
  - Image Quality Test (Including Resolution)
  - Optical Distortion Test
  - Saline Flow Rate Test
  - Leak 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

- **EMC and Electrical Safety**
  - UL Electrical Safety per ANSI/AAMI ES 60601-1:2005/(R)2012 and IEC 60601-2-18:2009
  - UL EMC per IEC 60601-1-2:2014 and IEC 60601-2-18:2009
- **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/Intraoperability 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 substantially equivalent to the predicate.