



Food and Drug Administration
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July 13, 2017

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

Re: K170660
Trade/Device Name: Endosee® Hysteroscope with Disposable Diagnostic (Dx) Cannula
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: Class II
Product Code: HIH, FAJ
Dated: June 14, 2017
Received: June 15, 2017

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,

Benjamin R. Fisher -S

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)
K170660

Device Name
Endosee Hysteroscope with Disposable Diagnostic (Dx) Cannula

Indications for Use (Describe)

The Endosee Hysteroscope and Disposable Diagnostic (Dx) Cannula are 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 Hysteroscope and Disposable Diagnostic (Dx) Cannula 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.

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510(k) Summary
Endosee® Hysteroscope with
Disposable Diagnostic (Dx) Cannula

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: June 14, 2017

Device Information

Trade Names: Endosee® Hysteroscope with Disposable Diagnostic (Dx) Cannula
Common Name: Hysteroscope, Cystoscope
Classification Number: Class II per 21 CFR 884.1690
Class II per 21 CFR 876.1500
Classification Name: Hysteroscope (And Accessories),
Cystoscope and Accessories (Flexible/Rigid)
Product Code: HIH, FAJ

Predicate Device Information

The Endosee® is substantially equivalent to the following predicates:

Primary Predicate: Schoelly Cystoscope/Hysteroscope and Accessories (K150158)
Additional Predicate: EndoSee U-Scope 8000 (K123151 & K132384)

The predicate devices have not been subject to a design-related recall.

Device Description

The Endosee system is a handheld, battery-operated endoscope that consists of two components: a reusable Handheld Monitor and a sterile, single use cannula. The Endosee is intended for use in viewing the cervical canal and uterine cavity for the purpose of performing diagnostic hysteroscopy procedures in an outpatient or in an office setting. The Endosee can also be used to permit viewing of the urinary bladder, via the urethra, for the purpose of performing diagnostic cystoscopy procedures in an outpatient or office setting.

The Disposable Diagnostic (Dx) Cannula is inserted through the cervix to view the cervical canal and uterine cavity. The Dx Cannula can also be inserted through the urethra to view the bladder. This enables the evaluation and diagnosis of the uterine cavity or the urinary bladder for pathology. The cannula includes a camera and LED light source at the distal end to illuminate the desired location for better user visualization, as well as to capture image and video of the diagnostic site. The video signal is electronically transferred to the Handheld Monitor of the Endosee Hysteroscope by an electrical connector, and an LCD touchscreen monitor on the reusable Handheld Monitor is used for viewing.

Product specifications are listed in the tables below:

Handheld Monitor

Parameter	Specification
Length	117.5mm
Diameter	29.8mm
Weight	90g
Diagonal Size of Display Area	88.9mm

Disposable Diagnostic (Dx) Cannula

Parameter	Specification
Cannula Type	Flexible
Cannula Length	276mm
Cannula Largest Outer Diameter	4.8mm
Field of View	100° ± 5°
Direction of View	20° ± 3°

Indications for Use

The Endosee Hysteroscope and Disposable Diagnostic (Dx) Cannula are 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 Hysteroscope and Disposable Diagnostic (Dx) Cannula 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

The substantial equivalence of the subject device to the predicates is discussed below in Table 1, by similarity in respect to: intended use, indications for use, principals of operation, technological characteristics, materials, and performance.

Table 1: Comparison of the Endosee to the Predicate Devices

Property	Subject Device Endosee Hysteroscope	Primary Predicate Schoelly Cystoscopes/ Hysteroscopes and Accessories	Additional Predicate Endosee U-Scope Model 8000	Significant Differences
510(k) Number	Not yet assigned	K150158	K123151; K132384	N/A
Indications for Use	<p>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 and pregnancy wastage, Evaluation of abnormal hystero-salpingogram, Intrauterine foreign body, Amenorrhea, Pelvic Pain</p> <p>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. The target population is all patients for whom a cystourethroscopy would be indicated, either in an office setting or in the operating room.</p>	<p>The Schoelly Cystoscopes/ Hysteroscopes and Accessories are indicated to provide the user with the means for endoscopic diagnostic and therapeutic surgical procedures. Examples for the use of the devices include the visualization and manipulation of anatomy as the surgeon deems appropriate. The Schoelly Cystoscopes/ Hysteroscopes and Accessories are intended to be used in general urological and gynecological surgery through a minimally invasive approach by utilizing natural orifices to access the surgical site.</p>	<p>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 and pregnancy wastage, Evaluation of abnormal hystero-salpingogram, Intrauterine foreign body, Amenorrhea, Pelvic Pain</p>	<p>Similar. Although the predicate is also indicated for the use in surgical procedures, the predicate and subject devices have the same intended use in general diagnostic gynecological or diagnostic urological procedures through a minimally invasive approach by utilizing natural orifices to access the diagnostic site.</p>
Technology Overview	<p>handheld battery-operated hysteroscope, consisting of a reusable handle and a sterile, disposable, diagnostic cannula</p>	<p>rigid reusable cystoscope/ hysteroscope to be used in conjunction with a light guide, light source, video camera, monitor, and printer for diagnostic and therapeutic surgical procedures</p>	<p>handheld battery-operated hysteroscope, consisting of a reusable handle and a sterile, disposable, diagnostic cannula</p>	<p>Different. However, the primary predicate and subject devices have technological characteristics typical for these types of devices, and do not raise any new questions of safety and effectiveness.</p> <p>The technological characteristics of the subject device are the same as the additional predicate.</p>

Cannula Type	Flexible	Rigid	Flexible	<p>Different. However, the primary predicate and subject devices have types of cannula that are typical for these types of devices, and do not raise any new questions of safety and effectiveness.</p> <p>The cannula type of the subject device is the same as the additional predicate.</p>
Patient Contacting Materials	glass, stainless steel, nylon, acrylic, adhesive	Stainless steel, stainless steel alloy, glass, glass fibers, adhesive, brazing alloy	glass, stainless steel, nylon, acrylic, adhesive	<p>Different. However, the primary predicate and subject devices have patient contacting materials that are typical for these types of devices, and do not raise any new questions of safety and effectiveness.</p> <p>The patient contacting materials of the subject device is the same as the additional predicate.</p>
Cannula Length	276mm	300mm - 365mm	276mm	<p>Different. However, the primary predicate and subject devices have cannula lengths that are typical for these types of devices, and do not raise any new questions of safety and effectiveness.</p> <p>The cannula length of the subject device is the same as the additional predicate.</p>
Cannula Largest Outer Diameter	4.8mm	2.9mm;4mm	4.8mm	<p>Different. However, the primary predicate and subject devices cannula outer diameters that are typical for these types of devices, and do not raise any new questions of safety and effectiveness.</p> <p>The cannula outer diameter of the subject device is the same as the additional predicate.</p>
Endoscope Light Source	LED	External, connected via light guide to light guide connector	LED	<p>Similar. Although the predicate utilizes an external light source and the subject device uses LEDs built into the cannula, both devices are the same in that light is transmitted through the endoscope to enhance visualization of the diagnostic site.</p> <p>The light source of the subject device is the same as the additional predicate.</p>
Endoscope Field of View	100° ±5°	70°-85°	100° ±5°	<p>Different. However, the primary predicate and subject devices have fields of view that are typical for these types of devices, and do not raise any new questions of safety and effectiveness.</p> <p>The field of view of the subject device is the same as the additional predicate.</p>

<p>Endoscope Direction of View</p>	<p>$20^{\circ} \pm 3^{\circ}$</p>	<p>$0^{\circ}-70^{\circ}$</p>	<p>$20^{\circ} \pm 3^{\circ}$</p>	<p>Different. However, the primary predicate and subject devices have directions of view that are typical for these types of devices, and do not raise any new questions of safety and effectiveness.</p> <p>The direction of view of the subject device is the same as the additional predicate.</p>
<p>Endoscope Image Display</p>	<p>LCD on handheld monitor</p>	<p>Camera/monitor connected to eyepiece</p>	<p>LCD on handheld monitor</p>	<p>Similar. Although, the primary predicate camera/monitor connects to an eyepiece for image display, both devices are the same in that they provide means of video endoscopy by displaying the diagnostic site on an external monitor.</p> <p>The endoscope display image of the subject device is the same as the additional predicate.</p>

Non-Clinical Performance Testing

As part of demonstrating substantial equivalence to the predicate devices, the following non-clinical performance tests were conducted:

- Design Validation
 - This validation of the subject device was performed on the device design in support of expanding the Endosee Hysteroscope with Disposable Diagnostic (Dx) Cannula indications for use to include cystoscopy applications. The purpose of the test was to determine that the subject device enables acceptable visualization of the bladder in a standard urological procedure as it is currently designed. The testing took place in a simulated operating room environment, utilizing cadaveric specimens. The acceptance criteria were that all participants must affirm that the cannula enabled visualization of all intended targets in the bladder. The subject device met all acceptance criteria.

Conclusion

The results of the testing described above demonstrate that the Endosee Hysteroscope with Disposable Diagnostic (Dx) Cannula is substantially equivalent to the predicate.