

MAR 08 2013

510(k) Summary
Prepared February 15, 2013

Sponsor: EndoSee Corp.

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Telephone: 650 397 5174

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Device Name: U-Scope Model 8000

Common Name: Hysteroscope

Classification:
Regulatory Class: II
Classification Regulation: 21 CFR 884.1690
Classification Panel: Obstetrics and Gynecology

A. Legally Marketed Predicate Devices

The EndoSee device is substantially equivalent to Microspan Hysteroscope manufactured by Imagyn Medical (K961688) and Gyrus ACMI Digital Hysteroscope manufactured by Gyrus ACMI (K092278).

B. Device Description:

The EndoSee U-Scope Model 8000 is a handheld, battery-operated portable hysteroscope. It includes a sterile single use disposable hysteroscopic cannula and a reusable handle. The disposable cannula contains a miniature CMOS camera and a light-emitting diode (LED) illumination module at the tip and a channel for infusion of irrigating fluid. The disposable cannula is sterilized and packaged in a sealed bag. The handle is light weight and ergonomically designed. It has a connector and locking mechanism for attaching and detaching the cannula. The handle contains the remaining electronics including a power on/off button, a video processor, a display unit (LCD display), a rechargeable battery, management electronics, microcontrollers and firmware.

C. Intended Use

The U-Scope device 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 uterine bleeding, infertility and pregnancy wastage; evaluation of abnormal hysterosalpingogram; intrauterine foreign body; amenorrhea; pelvic pain

D. Substantial Equivalence

The U-Scope 8000 is substantially equivalent to the Microspan Hysteroscope manufactured by Imagyn (K961688) and Gyrus ACMI Digital Hysteroscope manufactured by Gyrus ACMI (K092278) with regard to both intended use and technological characteristics as described in the tables below:

**Table 1
Comparison Table – Intended Use and Indications for Use**

| Feature | Subject Device U-Scope 8000 | Predicate 1 Imagyn Medical Microspan Hysteroscope (K961688) | Predicate 2 Gyrus ACMI Invisio Digital Hysteroscope System (K092278) |
|--------------------|--|---|---|
| Intended Use | Viewing of cervical canal and uterine cavity | Same | Same |
| Indication for use | The U-Scope device 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 uterine bleeding, infertility and pregnancy wastage; evaluation of abnormal hysterosalpingogram; intrauterine foreign body; amenorrhea; pelvic pain | The Microspan hysteroscope device is used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures | *The Gyrus ACMI Invisio Digital Hysteroscope is intended to be used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures. The Gyrus ACMI Invisio Digital Hysteroscope System: is intended to be used to process the video signal from the Invisio Digital Hysteroscope and ensure brightness, image clarity and color. Diagnostic Hysteroscopy: Abnormal uterine bleeding Infertility & pregnancy wastage 'Evaluation of abnormal hysterosalpingogrm |

K123151
Page 3 of 5

| | | | |
|---|---------------------------------|---------------------------------------|---|
| | | | Intrauterine foreign body Amenorrhea Pelvic pain Operative Hysteroscopy: <ul style="list-style-type: none"> • Directed biopsy • Removal of fibroids and polyps • Transection of intrauterine adhesions • Transection intrauterine septa |
| Intended Users | Trained Medical Professionals | Trained Medical Professionals | Trained Medical Professionals |
| Clinical application | Diagnostic hysteroscopy | Diagnostic and operative hysteroscopy | Diagnostic and operative hysteroscopy |
| Site of Use | Hospitals and Physician Offices | Hospitals and Physician Offices | Hospitals and Physician Offices |
| Class | II | II | II |
| Classification Regulation/ Product Code | 21 CFR 884.1690 HIH | 21 CFR 884.1690 HIH | 21 CFR 884.1690 HIH |

Table 2 Comparison Table – Technological Characteristics

| Feature | Subject Device U-Scope 8000 | Predicate 1 Imagyn Microspan Hysteroscope (K961688) | Predicate 2 Gyrus ACMI Invisio Digital Hysteroscope System (K092278) |
|------------------|--|--|---|
| Components | Design incorporates two separate components (cannula and handle) and incorporates a LCD monitor as an integral part of the handle. | Design incorporates stainless steel shaft, imaging fiber bundle, lens, eyepiece, light source and light cables | Design incorporates handle, semi rigid hysteroscope, digital CMOS sensor, PCBs, LED light source, electrical cords, power supply and cables |
| Battery Operated | Yes | No | No |
| Optical Image | Digital CMOS technology | Not specified in product labeling | Digital CMOS technology |
| Image | The CMOS sensor consists | Not specified in product | The CMOS sensor consists |

| | | | |
|--|---|--|--|
| Resolution | of approximately 160,000 pixels. | labeling | of approximately 100,000 pixels |
| Illumination Light source | LEDs at the distal tip of the cannula | Fiber optic bundle / external OES Xenon light source | Fiber optic bundle /integrated LEDs in the handle |
| Image transmission | Transmit images from a video camera to a video monitor | Eyepiece can be connected through an optical coupler to a camera | Transmit images from a video camera to a video monitor |
| Inflow and outflow channel for saline instillation | Single channel for inflow | None | In-flow and option for continuous flow with outside sheath |
| Sterile | Cannula is provided as sterile single use; Handle is provided non sterile | Provided non-sterile and requires sterilization by the end user | Provided non-sterile and requires sterilization by the end user |
| Disposable/ Reusable | Cannula is provided sterile for single use and the handle is reusable. | Reusable device, provided non-sterile which requires sterilization by the end user | Reusable device, provided non-sterile which requires sterilization by the end user |
| Shaft diameter and working length | Oval shape (3.8 mm x 4.6 mm) Working length 287 mm (11.3 in) | Not specified in product labeling | 5.5mm with continuous flow sheath Working length not available |
| Contact Materials | Compliant with ISO 10993 | Not specified in product labeling | Compliant with ISO 10993 |

E. Performance Data

Bench testing was conducted on the device to verify that it is compliant with biocompatibility requirements for a short duration indwelling device as specified in ISO 10993 – Part 1. It was also tested by a certified test laboratory and met the compliance requirements for electrical safety as specified in ISO 60601-1, including provisions for EMC safety in ISO 60601-1-2 and IEC 60601-2-18 Medical electrical equipment – Part 2-18: “Particular requirements for the basic safety and essential performance of endoscopic equipment”, including thermal safety at several points along the cannula. Mechanical characteristics were also tested with successful results. The software test data, including verification and validation results, were submitted as specified in FDA guidance documents related to requirements for software contained in medical devices. Other test data, as specified in FDA guidance documents related to 510(k) hysteroscopic devices included data on optics performance and results of image quality testing.

Sterilization validation and shelf life testing were conducted to confirm the label shelf life and are in compliance with the following:

- ISO 11135-1 Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical device
- ISO 11607 Packaging for Terminally Sterilized Medical Devices
- AAMI TIR12:2010 – Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

Handle reprocessing issues were addressed by test methodology described in AAMI TIR30:2011 – A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.

In addition, the following battery and mechanical characteristics bench tests were performed as follows:

- testing of battery specifications
- testing of durability of handle
- testing of effects of repeated bending, pulling, and torque
- testing of fluid delivery and controls

All of these performance verification and validation test results were provided in the submission according to requirements specified in FDA guidance documents.

F. Conclusion

In conclusion, the bench testing performed addressed materials, mechanical and electrical tests related to safety and effectiveness, and successful results demonstrated that the subject device is substantially equivalent to the predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 8, 2013

EndoSee Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
BUFFALO MN 55313

Re: K123151
Trade/Device Name: U-Scope Model 8000
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: February 26, 2013
Received: February 27, 2013

Dear Mr. Job:

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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 yours,

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): K123151

Device Name: U-Scope Model 8000

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Page 1 of 1

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and
Urological Devices
510(k) Number K123151