510(k) Summary

Sponsor: EndoSee Corporation

Contact Person: Xiaolong (Bruce) OuYang

Telephone: (650) 397-5174

Fax: (888) 388-1420

510(k) Summary Date: July 23, 2013

Device Name: U-Scope 8000 HSC+EMB Cannula

Common Name: Hysteroscope

Classification:

Regulatory Class: II

Review Category: 21 CFR 884.1690

Classification Panel: Obstetrics and Gynecology

Product Code: HIH (hysteroscope and accessories)

Legally Marketed Predicate Devices

The U-Scope Model 8000, EndoSee Corporation (K123151)

Endosampler, MedGyn Products, Inc. (K840383)

Device Description

The U-Scope 8000 HSC+EMB Cannula is a handheld, battery-operated portable hysteroscope. It includes a sterile single use disposable endometrial biopsy cannula (the U-Scope 8000 HSC+EMB cannula) and a reusable HandTower (U-Scope 8000). The disposable U-Scope 8000 HSC+EMB cannula contains a miniature CMOS camera and a light-emitting diode (LED) illumination module at its tip and two channels for infusion of irrigating fluid and aspiration of tissue. Adjacent to the tip of the cannula is a curette that facilitates collection of tissue during the biopsy procedure. The disposable cannula is sterilized and packaged in a sealed pouch. The HandTower is lightweight and ergonomically designed. It has a connector and locking mechanism for attaching and detaching the U-Scope 8000 HSC+EMB cannula. The HandTower contains the remaining electronics, including a power on/off button, a button to adjust the brightness of the LED, a button to allow capture of single images or start/stop a video of the procedure, a video processor, a display unit (LCD display), a rechargeable battery, management electronics, microcontrollers, and firmware.

Intended Use

The U-Scope 8000 HSC+EMB Cannula is used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures and to obtain an endometrial tissue sample (biopsy) in an outpatient or office setting. The sample is used for cytologic and histologic diagnosis. Generally recognized indications for diagnostic hysteroscopy include: abnormal bleeding, infertility and pregnancy wastage, evaluation of abnormal hysterosalpingogram, intrauterine foreign body, amenorrhea, and pelvic pain.

Substantial Equivalence

The submission device is substantially equivalent to the U-Scope Model 8000 manufactured by EndoSee Corporation (K123151) in terms of technological characteristics of the hand tower and to the Endosampler manufactured by MedGyn Products, Inc. (K840383) in terms of indication of use and technological characteristics of a biopsy cannula with curette.

Table I. Comparison of the U-Scope 8000 HSC+EMB Cannula to the Predicate Devices

	Subject device U-Scope 8000 HSC+EMB Cannula (this submission)	Predicate device Endosampler MedGyn Products Inc. (K840383)	Predicate device U-Scope Model 8000 EndoSee Corporation (K123151)
Indication for use	To permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures and to obtain an endometrial tissue sample (biopsy) in an outpatient or an office setting. The sample is used for cytologic and histologic diagnosis. Generally recognized indications for diagnostic hysteroscopy include: abnormal bleeding, infertility and pregnancy wastage, evaluation of abnormal hysterosalpingogram, intrauterine foreign body,	To obtain clearly differentiated endometrial tissue sample without anesthesia in an outpatient setting or in an office setting. The sample is used for cystologic and histologic diagnosis	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 hysterosalpingogram, intrauterine foreign body, amenorrhea, and pelvic pain.

	amenorrhea, and pelvic pain.		
Procedures	Uterine diagnostic and endometrial biopsy	Uterine diagnostic uses	Diagnostic hysteroscopy
Site of use	Hospitals and physician offices	Hospitals and physician offices	Hospitals and physician offices
Device Features			
Components	(1) image-capturing hand tower; (2) attachable cannula with outflow and inflow ports in which suction can be created and with a curette near its tip	Cannula with outflow port in which suction can be created and with a curette opening near its tip	(1) image-capturing hand tower; (2) attachable cannula with inflow port
Cannula Outer Diameter	4.3 mm	3 mm	3.8 x 4.6 mm (oval)
Cannula length	27 cm	21 cm	26 cm
Illumination light source	LEDs	N/A	LEDs
Image transmission	Image transmitted from a video camera to a video monitor on the handle	No image	Image transmitted from a video camera to a video monitor on the handle
LCD display size	3.5 inches (diagonal)	N/A	3 inches (diagonal)
Battery charge indication	Charge indication as an icon on the LCD monitor	N/A	No charge indication on the LCD monitor
Battery power	3.7 V	N/A	3.3 V
Adjust brightness of LEDs	Adjust by depressing a button on the hand tower	N/A	Brightness cannot be adjusted
Capture still or video images during procedure	Capture still or video during procedure by depressing a camera button on the hand tower	N/A	Cannot capture still or video during procedure
Enter patient ID information prior to procedure	User interface on monitor allows physician to add patient information	N/A	Cannot input patient information via the interface with the monitor

Duration of use	≤ 24 hours	≤ 24 hours	≤ 24 hours
Sterilization	HandTower is not sterile. The U-Scope 8000 HSC+EMB cannula is sterile following exposure to ethylene oxide (EO)	Exposure to ethylene oxide (EO)	Hand tower is not sterile. Diagnostic cannula sterile following exposure to ethylene oxide (EO)
Frequency of use	HandTower is reusable. The U-Scope 8000 HSC+EMB cannula is single patient use	Single patient use	Hand tower is reusable Diagnostic cannula is single patient use
Tissue contact materials	Compliant with ISO 10993	Compliant with ISO 10993	Compliant with ISO 10993

Performance Data

The U-Scope 8000 HSC+EMB Cannula was subjected to mechanical, temperature, field of view and image quality testing, in accordance with the FDA's "Hysteroscopic and Gynecologic Laparoscopes Submission Guidance" (1996).

Mechanical testing: The device was tested for bending, pulling, torque, and presence of leaks and following testing was found to meet design. The device was also tested for stiffness/force-to-tip deflection in comparison to other cleared endometrial sampling devices. This test served as a surrogate for an assessment of biopsy sampling quality.

Temperature testing: the device was measured for surface temperatures at various points over time and found to meet requirements specified in IEC 60601-2-18.

Field of View and Direction of Viewing testing: The device was tested for field of view accuracy and directions of view accuracy and found to meet requirements specified in ISO 8600-3.

Image Quality testing: The device was tested for image quality and found to meet requirements of ISO 8600-5.

The U-Scope 8000 HSC+EMB Cannula was tested for electrical and safety testing by a certified test laboratory and met the compliance requirements for electrical safety as specified in IEC 60601-1, including provisions for EMC safety in IEC 60601-1-2:2007 and IEC 61000-4-2:2008, as well as testing to IEC 60601-2-18:2009 Medical electrical equipment — Part 2-18: "Particular requirements for the basic safety and essential performance of endoscopic equipment," including thermal safety. Mechanical characteristics were also tested with successful results.

A series of biocompatibility testing, including cytotoxicity, sensitization, irritation, and acute systemic toxicity, demonstrated that the device components that are in contact with the patient are biocompatible.

Due to its labeling as sterile, the U-Scope 8000 HSC+EMB Cannula underwent sterilization validation and shelf life testing to confirm the label shelf life and was found in compliance with the following:

- ISO 11135-1:2007 Sterilization of health care products -- Ethylene oxide -Part 1: Requirements for development, validation and routine control of a sterilization process for medical device;
- ISO 11607-1:2006 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; and
- AAMI TIR 30:2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.

Conclusion

U-Scope 8000 HSC+EMB Cannula is substantially equivalent to its proposed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 2, 2014

EndoSee Corporation
Pin Yu
Vice President, Regulatory Affairs
4546 El Camino Road, Suite 215
Los Altos, CA 94022

Re: K132384
Trade/Device Name: U-Scope™ 8000 HSC+EMB Cannula
Regulation Number: 21 CFR§ 878.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: Class II
Product Code: HIH
Dated: June 3, 2014
Received: June 5, 2014

Dear Pin Yu,

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" (21CFR 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 yours,

Herbert P. Lerner -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

Indications for Use

510(k) Number (if known): K132384

Device Name: U-Scope 8000 HSC+EMB Cannula

Indications for Use:

The U-Scope 8000 HSC+EMB Cannula is used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures and to obtain an endometrial tissue sample (biopsy) in an outpatient or office setting. The sample is used for cytologic and histologic diagnosis. Generally recognized indications for diagnostic hysteroscopy include: abnormal bleeding, infertility and pregnancy wastage, evaluation of abnormal hysterosalpingogram, intrauterine foreign body, amenorrhea, and pelvic pain.

Prescription Use: ___X___ AND/OR Over-the-Counter Use: _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
2014.07.02 09:22:23 -04'00'