**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:** I  
- **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

<table>
<thead>
<tr>
<th>Subject device</th>
<th>Predicate device</th>
<th>Predicate device</th>
</tr>
</thead>
<tbody>
<tr>
<td>U-Scope 8000 HSC+EMB Cannula (this submission)</td>
<td>Endosampler MedGyn Products Inc. (K840383)</td>
<td>U-Scope Model 8000 EndoSee Corporation (K123151)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Indication for use</th>
<th>Subject device</th>
<th>Predicate device</th>
<th>Predicate device</th>
</tr>
</thead>
<tbody>
<tr>
<td>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,</td>
<td>To obtain clearly differentiated endometrial tissue sample without anesthesia in an outpatient setting or in an office setting. The sample is used for cytologic and histologic diagnosis</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Procedures</td>
<td>Uterine diagnostic and endometrial biopsy</td>
<td>Uterine diagnostic uses</td>
<td>Diagnostic hysteroscopy</td>
</tr>
<tr>
<td>------------</td>
<td>----------------------------------------</td>
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<td>------------------------</td>
</tr>
<tr>
<td>Site of use</td>
<td>Hospitals and physician offices</td>
<td>Hospitals and physician offices</td>
<td>Hospitals and physician offices</td>
</tr>
<tr>
<td>Device Features</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Components</td>
<td>(1) image-capturing hand tower; (2) attachable cannula with outflow and inflow ports in which suction can be created and with a curette opening near its tip</td>
<td>Cannula with outflow port in which suction can be created and with a curette opening near its tip</td>
<td>(1) image-capturing hand tower; (2) attachable cannula with inflow port</td>
</tr>
<tr>
<td>Cannula Outer Diameter</td>
<td>4.3 mm</td>
<td>3 mm</td>
<td>3.8 x 4.6 mm (oval)</td>
</tr>
<tr>
<td>Cannula length</td>
<td>27 cm</td>
<td>21 cm</td>
<td>26 cm</td>
</tr>
<tr>
<td>Illumination light source</td>
<td>LEDs</td>
<td>N/A</td>
<td>LEDs</td>
</tr>
<tr>
<td>Image transmission</td>
<td>Image transmitted from a video camera to a video monitor on the handle</td>
<td>No image</td>
<td>Image transmitted from a video camera to a video monitor on the handle</td>
</tr>
<tr>
<td>LCD display size</td>
<td>3.5 inches (diagonal)</td>
<td>N/A</td>
<td>3 inches (diagonal)</td>
</tr>
<tr>
<td>Battery charge indication</td>
<td>Charge indication as an icon on the LCD monitor</td>
<td>N/A</td>
<td>No charge indication on the LCD monitor</td>
</tr>
<tr>
<td>Battery power</td>
<td>3.7 V</td>
<td>N/A</td>
<td>3.3 V</td>
</tr>
<tr>
<td>Adjust brightness of LEDs</td>
<td>Adjust by depressing a button on the hand tower</td>
<td>N/A</td>
<td>Brightness cannot be adjusted</td>
</tr>
<tr>
<td>Capture still or video images during procedure</td>
<td>Capture still or video during procedure by depressing a camera button on the hand tower</td>
<td>N/A</td>
<td>Cannot capture still or video during procedure</td>
</tr>
<tr>
<td>Enter patient ID information prior to procedure</td>
<td>User interface on monitor allows physician to add patient information</td>
<td>N/A</td>
<td>Cannot input patient information via the interface with the monitor</td>
</tr>
</tbody>
</table>
### 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

**Conclusion**

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