DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 18, 2017

Interscope, Inc.
% Cynthia Nolte
Senior Director, Regulatory Affairs
Icon Clinical Research LLC
2100 Pennbrook Parkway
North Wales, PA 19454

Re: K170120
Trade/Device Name: EndoRotor
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and Accessories
Regulatory Class: Class II
Product Code: PTE
Dated: March 23, 2017
Received: March 24, 2017

Dear Cynthia Nolte:

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,

Joyce M. Whang -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

4. INDICATIONS FOR USE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170120

Device Name

EndoRotor

Indications for Use *(Describe)*

The EndoRotor is intended for use in endoscopic procedures by a trained gastroenterologist to resect and remove residual tissue from the peripheral margins following EMR (Endoscopic Mucosal Resection).

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
Interscope, Inc., EndoRotor®
(per 21CFR 807.92)

1. SUBMITTER/510(K) HOLDER

Interscope, Inc.
100 Grove Street, Suite 108
Worcester, MA 01605
Phone: 877-420-7299

Contact: Jeffery Ryan, Co-Founder, President & CEO
Contact Phone: 617-360-1168
Contact Email: Jeffery.ryan@interscopemed.com

Date Prepared: March 23, 2017

2. DEVICE NAME

Proprietary Name:	EndoRotor®
Classification Name:	Hysterscope and accessories
Classification Regulation:	21 CFR 884.1690
Product code:	*PTE*

3. PREDICATE DEVICE

Manufacturer:	Hologic, Inc.
Proprietary Name:	MyoSure Hysteroscopic Tissue Removal System
510(k) Number:	K142029
Classification Name:	Hysteroscope and accessories
Classification Regulation:	21 CFR 884.1690
Product Code:	HIH

4. DEVICE DESCRIPTION

The EndoRotor is a powered resection tool consisting of a power console, foot control, specimen trap with pre-loaded filter, and a single-use resection catheter that is inserted into the working channel of a compatible endoscope. The catheter consists of an outer cylindrical cannula attached to a braided catheter and a second inner cylindrical cannula positioned inside the lumen of the outer cannula. The inner tube has blades cut into the distal end, which is oriented adjacent to the distal end of the outer tube. A torque coil, located inside the braid, is attached directly to the inner tube, and provides rotation to the cutting tool when actuated by a foot pedal controlled drive motor. The inner tube rotates relative to the outer tube along its longitudinal axis to simultaneously cut tissue at the distal end only when the user actuates suction aspirating tissue through the lumen. The specimen is collected by a micron filter that is positioned in the flow path (in the single-

use specimen trap) that is mounted in a dedicated slot on the console.

5. INDICATION FOR USE/INTENDED USE

The EndoRotor is intended for use in endoscopic procedures by a trained gastroenterologist to resect and remove residual tissue from the peripheral margins following EMR (Endoscopic Mucosal Resection).

Contraindication:

The EndoRotor should not be used for the primary resection of lesions or for tissue intended for biopsy.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE/S

The proposed and predicate devices both consist of a cutting tool mounted on the distal end of a catheter that is inserted into the instrument channel of a compatible endoscope. The operator uses the cutting tool to resect mucosal tissue. The resection portion of both devices is single use.

The proposed EndoRotor performs the action of resection during the rotation of the inner cannula relative to the fixed outer cannula, with concurrent vacuum power. This resection method is similar to that of the Hologic Inc., MyoSure Hysteroscopic Tissue Removal System, except that when the tips resect, one is reciprocating and the other is rotational. The removal of the resected tissue is the same, i.e. with a vacuum source. Bench testing and an animal study performed in a porcine animal model under Good Laboratory Practice (GLP) supports the safety and effectiveness of the EndoRotor for the proposed indications for use.

The intended use of the proposed EndoRotor, for resection and removal of tissue, is the same as that of the predicate device (MyoSure Hysteroscopic Tissue Removal System), but the anatomical location is the gastrointestinal tract rather than the endometrium. The device is always under the control of a trained physician. The risks are the same and are technique dependent, not anatomically driven, i.e. to avoid cutting too deeply, to avoid perforations, to remove all of the tissue. Furthermore, both the proposed and predicate devices are intended to remove and aspirate tissue from similarly situated layers of tissue, which include a top mucosa layer – the endometrium in the uterus for the MyoSure and the mucosa of the gastrointestinal tract for the EndoRotor. The differences between gastrointestinal and uterine mucosa thickness is subtle at 1mm and 2mm respectively.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

The EndoRotor design was verified and validated through a series of physical and

mechanical performance tests on the catheter and console as well as animal testing. Testing of the catheter included sterilization validation with ethylene oxide residuals and pyrogenicity testing as well as biocompatibility testing. Shelf life testing and packaging validation and transport testing was conducted to support a 2-year shelf life for the packaged catheter. These tests included functional and simulated use testing which demonstrated conformance of the product with defined performance criteria out to 2 years.

Design verification testing performed on the console included power up and set up testing, foot pedal controls testing, functional testing, and torque testing. The console was also subjected to electrical safety and electromagnetic compatibility testing.

The safety and performance of the EndoRotor was evaluated in a porcine animal model. A total of 124 mucosal resections were created in the study distributed over 6 animals (4 recovery and 2 acute) and 3 organs (colon, stomach, esophagus). The following bleeding scoring system was used to evaluate the resections: 1 = self-limiting bleeding, resolves in under 2 minutes; 2 = self-limiting, bleeding resolves in greater than 2 minutes without intervention; 3 = resolves with intervention. Out of 122 resection sites scored, 97 had mild bleeding (79.5%), 24 had moderate bleeding (19.7%), and one site (0.82%) had severe bleeding which resolved after epinephrine administration. All animals tolerated the treatment procedures and survived to the scheduled necropsy time point. Out of those, there were perforations at 2 sites in the colon (1.6% of total sites) both in the acute group. In both of these cases, perforation was related to inadequate (too deep) pre-resection submucosal injection, rather than the device itself. Microscopic evaluation of the resection sites confirmed that the submucosa or, rarely, the muscularis mucosa was the deepest affected layer through all of the resections. The results show that use of the EndoRotor system for mucosal tissue resection in the porcine esophagus, stomach, and colon was associated with favorable and clinically acceptable tissue responses.

An evaluation was completed to determine that when proper procedure is followed as provided in the labeling, including a post procedure flush, there is no residual specimen in the catheter. The study confirms that the entire specimen is captured by the specimen trap.

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Usability studies were conducted to evaluate the clinical performance of the proposed EndoRotor. The results confirmed that all system requirements related to usability were met.

9. SUMMARY OF OTHER INFORMATION

No other information was submitted.

10. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Interscope concludes that the EndoRotor is substantially equivalent to the Hologic MyoSure Hysteroscopic Tissue Removal System. The results of bench testing, a GLP animal study and usability studies support the safety and effectiveness of the EndoRotor for the proposed indications for use. A comparison table is provided in Table 1.

Table 1. Comparison Table for Determination of Substantial Equivalence

	PROPOSED DEVICE	PREDICATE DEVICE
Sponsor	Interscope, Inc.	Hologic, Inc.
Device name	EndoRotor	MyoSure Hysteroscopic Tissue Removal System
Regulatory Status	Proposed	K142029
Regulation Number	21CFR 884.1690	21CFR 884.1690
Regulation Name	Hysteroscope and accessories	Hysteroscope and accessories
Indications for Use	The EndoRotor is intended for use in endoscopic procedures by a trained gastroenterologist to resect and remove residual tissue from the peripheral margins following EMR (Endoscopic Mucosal Resection).	The MyoSure Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue such as: • submucous myomas • endometrial polyps • retained products of conception.
Components	• Control unit including peristaltic pump, motor drive and pinch valve • Catheter with cutting device mounted on distal end • Foot control to control drive motor • Specimen trap with pre-loaded micron filter	The MyoSure Hysteroscopic Tissue Removal System consists of the following components: • MyoSure Control Unit: contains an electric motor and software controller that drive that MyoSure Tissue Removal Device • MyoSure Tissue Removal Device: A tissue morcellator that is connected to the Control Unit via a flexible drive cable • MyoSure Foot Pedal: activates and deactivates the MyoSure Control Unit
Principle of Operation	Mechanical resection using a cutting cannula with simultaneous aspiration	Mechanical resection using rotation and reciprocation of the cutter with simultaneous aspiration
Reuse status	Single use	Single use