January 3, 2019

Interscope, Inc.
% Cynthia Nolte
Director, Regulatory
ICON Clinical Research LLC
2100 Pennbrook Parkway
North Wales, Pennsylvania 19454

Re: K181127
Trade/Device Name: EndoRotor Console, EndoRotor Catheters, EndoRotor Specimen Trap, EndoRotor Filter Set, EndoRotor Foot Control
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and Accessories
Regulatory Class: Class II
Product Code: PTE
Dated: December 13, 2018
Received: December 14, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel G. Walter Jr -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

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)*
K181127

Device Name
Endo Rotor®

Indications for Use *(Describe)*
The EndoRotor® is intended for use in endoscopic procedures by a trained gastroenterologist to resect and remove tissue, not intended for biopsy, of the gastrointestinal (GI) system including post-endoscopic mucosal resection (EMR) tissue persistence with a scarred base and residual tissue from the peripheral margins following EMR.

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

Modification to the Interscope, Inc., EndoRotor®: Generation 2 (Gen 2)
(per 21CFR 807.92)

1. SUBMITTER/510(K) HOLDER

Interscope, Inc.
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Date Prepared: December 4, 2018

2. DEVICE NAME

Proprietary Name:	EndoRotor®
Classification Name:	Endoscopic Morcellator Gastroenterology
Regulation Name:	Hysteroscope and accessories
Classification Regulation:	21 CFR 884.1690
Product code:	PTE

The EndoRotor®, with the design modifications and expanded indications for use described in the current 510(k) premarket notification, will continue to be marketed as the EndoRotor®.

3. PREDICATE DEVICE

Manufacturer:	Interscope, Inc.
Proprietary Name:	EndoRotor®
Classification Name:	Endoscopic Morcellator Gastroenterology
510(k) Number:	K170120
Regulation Name:	Hysteroscope and accessories
Classification Regulation:	21 CFR 884.1690
Product Code:	PTE

4. DEVICE DESCRIPTION

The purpose of the current 510(k) Premarket Notification is to obtain clearance for modifications to the EndoRotor® design to expand the range of catheters available to gastroenterologists and improve the flexibility and ease of use of the device. In addition, the indications for use for the EndoRotor® have been clarified to include post-endoscopic mucosal resection (EMR) persistent tissue with a scarred base.

The EndoRotor®, with the design modifications and expanded indications for use described in the current 510(k) premarket notification, will continue to be marketed as the EndoRotor®. The new EndoRotor® will be referred to as the "modified EndoRotor" in this 510(k) Summary.

The overall device description remains unchanged since initial FDA clearance. Both the predicate and modified EndoRotor® are powered resection tools 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 design modifications to the EndoRotor® described in the current 510(k) premarket notification include enhancements to improve the ease of use of the console and catheter components as well as provide flexibility to the gastroenterologist.

5. INDICATION FOR USE/INTENDED USE

The EndoRotor® is intended for use in endoscopic procedures by a trained gastroenterologist to resect and remove tissue, not intended for biopsy, of the gastrointestinal (GI) system including post-endoscopic mucosal resection (EMR) tissue persistence with a scarred base and residual tissue from the peripheral margins following EMR.

The indications for use for the EndoRotor® described in the current 510(k) premarket notification were clarified to include post EMR persistent tissue with a scarred base. The modified EndoRotor® continues to be indicated to resect and remove residual tissue from the peripheral margins following EMR.

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

Both the modified and predicate EndoRotor® devices are powered resection tools consisting of a power console, foot control, specimen trap with preloaded filter and a single-use resection catheter that is inserted into the working channel of a compatible endoscope. Resection of residual tissue with the catheter is achieved through reciprocating and rotational movement of the inner cannula relative to the fixed outer cannula while removal is performed via vacuum suction. The device is always under the control of a trained physician and is technique dependent with regards to depth of removal and avoiding perforation.

To improve the flexibility, performance, and ease of use of the system, Interscope has implemented design enhancements to the catheter and console components as described below.

Console

The console houses the control panel, drive motor, vacuum control valve, and peristaltic irrigation pump drive. The principles of operation and overall characteristics of the modified

EndoRotor® Console remain unchanged since initial clearance (K170120).

The console was modified to "Generation 2" (Gen2) to improve usability and ease of use as described in Table 5-1.

Table 5-1. EndoRotor Gen2 Console Design Changes

Design Change	Justification of Design Change
New Mechanical Irrigation Pump	Offers improved usability and component quality.
Addition of Lavage Button	Allows user to enable or disable irrigation flow. Improves usability, giving user control of irrigation to improve the field of view of the resection site.
Reduction in Irrigation Flow Rate	Reduction in the irrigation flow rate from 5-12mL/min to a fixed 5mL/min. Improves usability, providing better visibility to the resection site.
Increase in Prime Flow Rate	Increase in the prime flow rate from 4mL/min to 25 mL/min and duration from 10 to 25 seconds. Improves usability by allowing complete priming with one button push.
Increase in Pitch Valve Open Timing	Increase in the pinch valve open timing during load from 10 to 25 seconds. Improves usability by enabling increased prime flow rate.

Catheter

The catheter design was updated to produce "Generation II" (Gen2) catheters; overall design principles are the same. All catheters include a debriding cutter and support functions of lavage and aspiration from the anatomical site through the endoscope working channel to the EndoRotor® Specimen Trap.

Design for all catheters was enhanced per Table 5-2 to provide more options to the clinician and procedure and improve performance. Additionally, Interscope has added two (2) new catheters. The two (2) new catheters (bolded in table below) were added to increase cutting efficiency. An overview of all available catheters and characteristics are provided in Table 5-3.

Table 5-2. EndoRotor® Gen2 Catheter Design Changes

Design Change	Justification of Design Change	Applicability to Catheters
New cutting window[1] orientation interface, reinforced outer braided shaft, added Mobilize® lubricious additive to outer braided shaft	Enables improved performance of orienting the cutting window of the catheter to the target tissue.	ER 10-01-OP[2] ER 10-02-O[3] ER 10-03-OP[4] **ER 10-03-OP-S** **ER 10-03-F-S**
Modified catheter lengths	To expand compatibility with the range of endoscope on the market.	**ER 10-03-OP-S** **ER 10-03-F-S**
Expanded cutting window geometry	To address limitations in certain anatomical locations (i.e., frontal face resection)	
Added serrated teeth to inner and outer cutters	To increase cutting efficiency	

1 New cutting window only applies to bolded catheters
2 Revised part number – originally cleared (K170120) as part no. ER 10-01
3 Revised part number – originally cleared (K170120) as part no. ER 10-02
4 Revised part number – originally cleared (K170120) as part no ER 10-03

Table 5-3. Gen2 EndoRotor® Catheters

Part No.	Length	Compatible Endoscopes	Window Size	Cutter Serrated teeth placement
ER 10-01-OP[1]	3.2mm x 1890mm	Olympus colonoscopes 3.2mm x 1680mm; Pentax colonoscopes 3.2 mm x 1700mm	3.0mm^2	Inner cutter
ER 10-02-O[2]	3.2mm x 1540mm	Olympus colonoscopes 3.2mm x 1330mm		Inner cutter
ER 10-03-OP[3]	3.2mm x 1240mm	Olympus gastroscopes 3.2mm x 1030mm; Pentax gastroscopes 3.2mm x 1050mm		Inner cutter
ER 10-03-OP-S	**3.2mm x 1240mm**	**Olympus gastroscopes 3.2mm x 1030mm; Pentax gastroscopes 3.2mm x 1050mm**	**4.4 mm^2**	**Inner and outer cutter**
ER 10-03-F-S	**3.2 mm x 1270 mm**	**Fuji gastroscopes 3.2 mm x 1100 mm**		**Inner and outer cutter**

1Revised part number – originally cleared (K170120) as part no. ER 10-01
2Revised part number – originally cleared (K170120) as part no. ER 10-02
3Revised part number – originally cleared (K170120) as part no ER 10-03

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

Interscope has completed verification testing to support the Catheter and Console design changes, as summarized in Section 6 of this 510(k) summary. Testing executed was limited to the design changes and met all acceptance criteria as summarized in Table 5-4.

Table 5-4. Testing to Support Gen2 Design Changes

EndoRotor® Component	Testing Performed	Results
EndoRotor® Catheter	• Biocompatibility Testing • Functional Testing	• All components biocompatible • All acceptance criteria met
EndoRotor® Console	• Power-up and Set-up Testing • Functional Testing	• All acceptance criteria met

The EndoRotor® design, as cleared under K170120, was verified and validated through a series of physical and mechanical performance tests on the catheter and console as well as animal testing. Those tests that are applicable to the modified EndoRotor® are summarized in Table 5-5.

Table 5-5. Non-Clinical Performance Testing of EndoRotor® Cleared Under K170120 Applicable to the Modified EndoRotor®

EndoRotor® Component	Testing Performed
EndoRotor® Catheter	• Sterilization validation • Pyrogenicity testing • Shelf-life • Packaging validation • Transport testing
EndoRotor® Console	• Design verification testing • Electrical Safety and Electromagnetic Compatibility Testing
Animal Testing	The safety and performance of the EndoRotor® was evaluated in a porcine animal model which included one hundred and twenty-four (124) mucosal resections over 6 animals (4 recovery and 2 acute) and 3 organs (colon, stomach, esophagus). All animals tolerated the treatment well and results showed the EndoRotor® system was associated with favorable and clinically acceptable tissue response. Design validation and usability assessment were completed in a porcine model with (4)

EndoRotor® Component	Testing Performed
	additional animals without complication. No difference was noted in the safety profile of the device.
Procedural Testing	Specimen Trap: EndoRotor® was evaluated 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.

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Usability studies were conducted to evaluate the clinical performance of the predicate EndoRotor®. The modifications to the console and catheter were made to improve EndoRotor® performance for tissue resection and removal in procedures where biopsy is not required. The results confirmed that all system requirements related to usability were met. These studies are applicable to the modified EndoRotor®.

An investigator-led study was conducted to support the safety and effectiveness of the EndoRotor® for post-endoscopic mucosal resection (EMR) persistent tissue with a scarred base. Gastroenterologists in Queens Alexandra Hospital, located in Portsmouth, United Kingdom, completed an investigator-led series utilizing the predicate EndoRotor® in management of post EMR tissue persistence with a scarred base. In a pending peer review manuscript Khandiah K, Subramanian S, Thayalasekaran S, Chedgy F and Bhandari P. Nineteen (19) patients were referred to Queens Alexandra Hospital, a tertiary center, following diagnosed tissue persistence following EMR. Scarred sites of the colon, in each of the nineteen (19) patients, were evaluated by physicians and found to have lesions determined difficult to resect and no longer amenable to EMR due to scarring from previous EMR. The EndoRotor® was used to perform resection of the identified patient site and successfully demonstrated the ability to superficially resect the scarred areas. The procedure outcomes using the EndoRotor® ensured muscle and luminal preservation in addition to disease eradication in fifteen (15) patients in twenty-one (21) procedures (1.4 procedure average) with no incidences of perforation or delayed bleeding; all patients were seen at follow up n=4 months. Study outcomes showed EndoRotor® directly led to successful avoidance of surgery in 78.9% of patients

Physicians in Western Europe (Austria, Germany, The Netherlands, Switzerland and the United Kingdom) completed seventy-eight (78) commercial EndoRotor® procedures to treat the aforementioned scarred lesions. Similarly disease eradication and luminal preservation was achieved within two (2) procedures or less with seventy (70) patients requiring one (1) treatment and eight (8) patients requiring two (2) procedures without complication.

The compiled data provides real world clinical evidence to support the expanded indications for use. The clinical experience outlined in this Premarket Notification supports the clinical safety and efficacy of the EndoRotor for use in the expanded indications.

9. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Interscope concludes that the modified EndoRotor® is substantially equivalent to the predicate EndoRotor® cleared by FDA (K170120). The results of bench testing to verify the performance of the Gen2 catheters and console, in addition to the thirty eight (38) procedures demonstrating successful treatment of post EMR tissue persistence, support the safety and effectiveness of the modified EndoRotor for the expanded indications for use. A comparison of the currently marketed EndoRotor® and the EndoRotor®: Gen2 is provided in Table 5-6.

Table 5-6. Side-by-Side Comparison for Determination of Substantial Equivalence

	Proposed Device	Predicate	Same/Different
Sponsor	Interscope, Inc.	Interscope, Inc.	
Device name	EndoRotor®	EndoRotor®	Same
Regulatory Status	Proposed	K170120	N/A
Device Classification Code/Name	PTE – Endoscopic Morcellator Gastroenterology	PTE – Endoscopic Morcellator Gastroenterology	Same
Regulation Number	21CFR 884.1690	21CFR 884.1690	Same
Regulation Name	Hysteroscope and accessories	Hysteroscope and accessories	Same
Indications for Use	The EndoRotor® is intended for use in endoscopic procedures by a trained gastroenterologist to resect and remove residual tissue, not intended for biopsy, of post endoscopic mucosal resection (EMR) tissue persistence with a scarred base, and residual tissue from the peripheral margins following EMR.	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 EndoRotor® should not be used for tissue intended biopsy.	Same: -Intended Use - clarification on original intended use post EMR tissue persistence with a scarred base Different: - Addition of EMR tissue persistence with a scarred base
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	• 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	Different: - Three (3) new catheters will be available; two (2) to accommodate endoscope variability among manufactures and one (1) to support faster tissue acquisition
Principle of Operation	Mechanical resection using a cutting cannula with simultaneous aspiration	Mechanical resection using a cutting cannula with simultaneous aspiration	Same
Reuse status	Single use	Single use	Same