December 13, 2019

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

Re: K190715
Trade/Device Name: EndoRotor Console, EndoRotor Catheter, EndoRotor Specimen Trap, EndoRotor Filter Set, EndoRotor Roll Stand
Regulation Number: 21 CFR 874.4250
Regulation Name: Ear, nose, and throat electric or pneumatic surgical drill
Regulatory Class: Class II
Product Code: ERL
Dated: November 11, 2019
Received: November 12, 2019

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Michael Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190715

Device Name
EndoRotor Airway Debridement System

Indications for Use *(Describe)*
The EndoRotor® System is intended for use in airway procedures including removal of granulation tissue and endobronchial lesions.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K190715

510(K) SUMMARY

EndoRotor® Airway Microdebridement System
(per 21CFR 807.92)

1. SUBMITTER/510(K) HOLDER

Interscope, Inc.
100 Main Street, Suite 108
Whitinsville, MA 01588
Phone: +1 877-420-7299

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

Date Prepared: December 12, 2019

2. DEVICE NAME

Proprietary Name:	EndoRotor®
Classification Name:	Drill, surgical, ENT (electric or pneumatic) including handpiece
Regulation Name:	Ear, nose, and throat electric or pneumatic surgical drill
Classification Regulation:	21 CFR 874.4250
Product code:	ERL

3. PREDICATE AND REFERENCE DEVICES

Predicate device

Manufacturer:	Medtronic XOMED
Proprietary Name:	XPS 3000 System
Classification Name:	ENT Surgical Drill
510(k) Number:	K041413
Regulation Name:	Ear, nose, and throat electric or pneumatic surgical drill
Classification Regulation:	21 CFR 874.4250
Product Code:	ERL

Reference Device

Manufacturer:	Interscope, Inc.
Proprietary Name:	EndoRotor®
Classification Name:	Endoscopic Morcellator Gastroenterology
510(k) Number:	K181127
Regulation Name:	Hysterscope and accessories
Classification Regulation:	21 CFR 884.1690
Product code:	PTE

4. DEVICE DESCRIPTION

The EndoRotor® Airway Microdebridement System is a powered resection tool consisting of a power Console with Foot Control, Specimen Trap with pre-loaded filter, and a single-use Catheter with a cutting tool mounted on the distal end. The EndoRotor's flexible design allows it to be used within the working channel of flexible bronchoscopes in tortuous paths.

The Console houses the control panel, drive motor, vacuum control valve, and peristaltic irrigation pump drive. The Catheter includes a debriding cutter and allows for aspiration from the resection site through the bronchoscope working channel to the Specimen Trap.

5. INDICATION FOR USE/INTENDED USE

The EndoRotor® System is intended for use in airway procedures including removal of granulation tissue and endobronchial lesions.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE

Table 1. Side-by-Side Comparison for Determination of Substantial Equivalence

	Subjects	Predicate	Comparison
Sponsor	Interscope, Inc.	Medtronic XOMED	
Device name	EndoRotor®	XPS 3000 System	
Regulatory Status	Proposed	K041413	
Device Classification Code/Name	ENT Surgical Drill	ENT Surgical Drill	
Regulation Number	21CFR 874.4250	21CFR 874.4250	
Regulation Name	Ear, nose and throat electric or pneumatic surgical drill	Ear, nose and throat electric or pneumatic surgical drill	
Indications for Use	The EndoRotor® System is intended for use in airway procedures including removal of granulation tissue and endobronchial lesions.	Nasopharyngeal / laryngeal indications include adenoidectomy, tracheal procedures, laryngeal polypectomy, laryngeal lesion debulking, tonsillectomy, tonsillotomy for obstructive tonsillar disease, removal of endobronchial lesions, and the surgical management of recurrent respiratory papillomatosis (RRP).	The indications for use for the EndoRotor® are limited to airway procedures, which are a subset of the predicate indications.
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 • Handpiece with cutting tool mounted on distal end • Foot control to control drive motor	• The EndoRotor® includes a specimen trap to collect tissue samples as needed. • The EndoRotor® bypasses the use of a hand piece and rotates using a multi filar torque cable attached directly to the console instead of a hand piece interface to both the cutting tool and console.
Resection site access	Flexible bronchoscope	Rigid bronchoscope	The use of a flexible bronchoscope allows EndoRotor® to access distal sites in the airway. Simulated

	Subjects	Predicate	Comparison
			use testing of the EndoRotor® in a test system created based on the anatomical requirements of the human lung showed the EndoRotor® successfully met all functional requirements.
Principle of Operation	Mechanical resection using a rotational cutting cannula with simultaneous aspiration	Mechanical resection using rotational movement and oscillation of the cutting blade with simultaneous aspiration	Both proposed and predicate devices use rotational movement for resection of soft tissue. Oscillation includes a counter rotation every third revolution for use with sinus and bone resection which is not indicated for the EndoRotor.
Speed	High: 1000-1750 RPM Low: 500-1750 RPM	500-5,000 RPM oscillate 500-12,000 RPM forward	The EndoRotor® rotation speeds are within the operating range of the predicate. The EndoRotor® is not indicated for bone resurfacing functions that require higher speeds.
Reuse status	Resection cannula: Single use	Resection blade: Single use	Same

Both the proposed EndoRotor® Airway Microdebridement System and the predicate XPS 3000 System are powered resection tools consisting of a power Console, Foot Control, and a single-use cutting tool. The system will be offered with two choices of rotation speeds, either low 500 RPM/high 1000 RPM or low 1000 RPM/high 1750 RPM.

The disposable Catheter supplied for use with the proposed EndoRotor® Airway Microdebridement System includes a debriding cutter and provides aspiration from the site to a Specimen Trap. The cutting tool consists of an outer cylindrical cannula attached to a flexible braided Catheter and a second inner cylindrical cannula positioned inside the lumen of the outer cannula. Microdebridement is achieved through rotational movement of the inner cannula relative to the outer cannula. The Catheter accesses the resection site via a flexible bronchoscope. Simulated use testing confirms that the Catheter functions as designed in a tortuous path.

The EndoRotor® Catheter attaches directly to the Console that provides operational control for the Catheter and includes the drive motor and vacuum control. The Console also houses a peristaltic irrigation pump to provide lavage as needed.

The predicate XPS 3000 System cutting tools used for airway procedures have straight and bent shafts of varying lengths with sharp edges that are mounted in a Handpiece. Microdebridement is achieved via rotational movement of an inner cylindrical cannula positioned inside the lumen of the outer cannula, with an oscillation sequence. The Catheter has a continuously variable oscillation speed of 500-5000 RPM. The mode of operation and speed is set and displayed on the Console. The resection site is accessed via a rigid bronchoscope.

The overall design and operation of the EndoRotor® Airway Microdebridement System are

identical to that of the XPS 3000 System. The EndoRotor® blade design is markedly similar to that of the Tricut blade supplied for use with the predicate device, as well as other sinus debriders. Technical differences between the proposed and predicate debriders are limited to the type of bronchoscope used for accessing the resection site (flexible vs rigid), and the oscillation sequence incorporated into the movement of the predicate cutting tool.

The design and operation of the proposed EndoRotor® Airway Microdebridement System is identical to the EndoRotor® cleared for gastrointestinal use, most recently as K181127 (reference device). The only difference is a decrease in the length of the Catheter supplied for use in airway procedures to accommodate the length of the compatible bronchoscopes vs gastroscopes/colonoscopes. Functional performance testing of the shorter Catheter passed all acceptance criteria.

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

The EndoRotor® Airway Microdebridement System was verified and validated through a series of physical and mechanical performance tests on the Catheter and Console. These tests are summarized in Table 2.

Table 2. Non-Clinical Performance Testing

EndoRotor® Component	Testing Performed	
EndoRotor® Catheter	• Biocompatibility • Sterilization validation • Pyrogenicity • Shelf-life • Packaging validation • Transport testing • Functional testing*	Met established acceptance criteria
EndoRotor® Console	• Design verification testing • Power-up and Set-up Testing • Functional Testing • Electrical Safety and Electromagnetic Compatibility Testing	Met established acceptance criteria
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.	

*Includes functional performance testing of the EndoRotor® Catheter developed for airway procedures.

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

No clinical study was conducted to support the 510(k) Premarket Notification. The EndoRotor has been cleared for use in the gastrointestinal system (K181127). The safety and performance of the EndoRotor has been demonstrated for use throughout the alimentary tract, a region where tissue walls less than 2mm, consisting of mucosa/submucosa/muscularis propria, have higher risk to injury with cutting instruments. The evidence supports the clinical performance of EndoRotor for airway debridement.

9. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Based on the information summarized above, Interscope concludes that the EndoRotor® Airway Microdebridement System is substantially equivalent to the predicate XPS 3000

System. The bench testing (including simulated use testing to evaluate functional performance for airway procedures), animal testing, and usability testing support the safety and effectiveness of the EndoRotor® Airway Microdebridement System for use in airway procedures.