DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 9, 2017

Laurimed LLC
Mr. Brian DuBois
General Manger
500 Arguello St., Suite 100
Redwood City, CA 94063

Re: K163247
Trade/Device Name: PolypVac Microdebrider
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: February 8, 2017
Received: February 9, 2017

Dear Mr. DuBois:

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,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat 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)*

K163247

Device Name

PolypVac Microdebrider

Indications for Use *(Describe)*

The PolypVac Microdebrider is a shaver system intended for the resection of soft tissue and thin bone as part of the following endoscopic sinus procedures: ethmoidectomy, maxillary antrostomy, polypectomy, turbinectomy / turbinate reduction, sphenoidotomy, and frontal recess dissection.

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 – K163247

I. General Information [807.92(a)(1)]

Name, Address, Phone and Fax Number of Applicant

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Date Prepared

February 8, 2017

II. Device Information [§807.92(a)(2)]

Trade Name: PolypVac Microdebrider
Common Name: Microdebrider
Classification Name: Ear, nose, and throat electric or pneumatic drill
Classification: 21 CFR §874.4250
Product Code: ERL
Device Class: Class II

III. Predicate Device [§807.92(a)(3)]

The subject PolypVac Microdebrider is substantially equivalent to the primary predicate, the PolypVac Microdebrider (K161101), and the secondary predicate, the Medtronic Xomed XPS 3000 (K041413).

IV. Device Description [§807.92(a)(4)]

The PolypVac Microdebrider is a shaver system intended for the resection of soft tissue and thin bone as part of endoscopic sinus procedures. The system consists of a hand-held cutting device, tissue filter, and stylet. The PolypVac Microdebrider is supplied sterile and is single-use and disposable.

V. Indications for Use [§807.92(a)(5)]

The PolypVac Microdebrider is a shaver system intended for the resection of soft tissue and thin bone as part of the following endoscopic sinus procedures: ethmoidectomy, maxillary antrostomy, polypectomy, turbinectomy / turbinate reduction, sphenoidotomy, and frontal recess dissection.

VI. Comparison of Technological Characteristics with the Predicate Device [§807.92(a)(6)]

The technological characteristics and principles of operation of the subject PolypVac Microdebrider are substantially equivalent to the PolypVac Microdebrider primary predicate device (K161101) and the Medtronic Xomed XPS 3000 secondary predicate device (K041413).

Table 1: Summary of Technological Characteristics

Model Name	**PolypVac Microdebrider** (Primary Predicate)	**Xomed XPS 3000** (Secondary Predicate)	**PolypVac Microdebrider**	**Rationale for Substantial Equivalence**
Device Trade Name	**PolypVac Microdebrider**	**XPS 3000 System**	**PolypVac Microdebrider**	
510(k) Number	**K161101**	**K041413**	**K163247**	
Product Code	ERL	ERL	ERL	Same.
Intended Use	Intended for the resection of soft tissue during sinonasal polypectomy.	Intended for the incision and removal of soft and hard tissue or bone in general otorhinolaryngology, head and neck, and otoneurological surgery.	Intended for the resection of soft tissue and thin bone in endoscopic sinus procedures.	Both the subject PolypVac Microdebrider and the Xomed XPS 3000 are intended for the resection of soft tissue and thin bone during otorhinolaryngology procedures.
Indications for Use	Indicated for the excision of polyps in the nasal passageways and in sinuses for which access has been previously established.	The XPS 3000 is intended for the incision and removal of soft and hard tissue or bone in general otorhinolaryngology, head and neck, and otoneurological surgery. *(non-applicable sections removed)* Sinus indications include: Septoplasty, removal of septal spurs, **POLYPECTOMY**, **ANTROSTOMY**, **ETHMOIDECTOMY** / sphenoethmoidectomy, frontal sinus trephination and irrigation, frontal sinus drill out, endoscopic DCR, trans-spheniodal procedures, maxillary sinus **POLYPECTOMY**, circumferential **MAXILLARY ANTROSTOMY**, choanal atresia, **SPHENOIDOTOMY**, and medial, lateral, and posterior **FRONTAL SINUSOTOMY**. *(non-applicable sections removed)*	The PolypVac Microdebrider is a shaver system intended for the resection of soft tissue and thin bone as part of the following endoscopic sinus procedures: ethmoidectomy, maxillary antrostomy, polypectomy, turbinectomy / turbinate reduction, sphenoidotomy, and frontal recess dissection.	Both the subject PolypVac Microdebrider and the Xomed XPS 3000 are indicted for: • Ethmoidectomy • Maxillary Antrostomy • Polypectomy • Turbinectomy / Turbinate Reduction • Sphenoidotomy • Frontal recess dissection
Contraindications	None	None	None	Same.
Target Population	Patients with accessible sinonasal polyps	Patients in otorhinolaryngology, head and neck, otoneurology, lipoplasty, and orthopedic procedures.	Patients in otorhinolaryngology procedures.	Both the subject PolypVac Microdebrider and the Xomed XPS 3000 serve patients who would benefit from otorhinolaryngology procedures.
Anatomic Sites	Nose (including accessible sinuses)	Nasal passageways, sinuses, nasopharynx, larynx, ear, head and neck, and various anatomic locations associated with lipoplasty and/or orthopedic procedures.	Nasal passageways and sinuses.	Both the subject PolypVac Microdebrider and the Xomed XPS 3000 are intended for use in the nasal passageways and sinuses.

Model Name	**PolypVac Microdebrider** (Primary Predicate)	**Xomed XPS 3000** (Secondary Predicate)	**PolypVac Microdebrider**	**Rationale for Substantial Equivalence**
Device Trade Name	**PolypVac Microdebrider**	**XPS 3000 System**	**PolypVac Microdebrider**	
510(k) Number	**K161101**	**K041413**	**K163247**	
Target Tissue	Sinonasal Polyps	Various soft and hard tissues encountered during otology, otorhinolaryngology, head and neck, lipoplasty, and orthopedic procedures.	Various soft and hard tissues encountered during otorhinolaryngology procedures.	Both the subject PolypVac Microdebrider and the Xomed XPS 3000 are intended for the resection of various soft and hard tissues encountered during otorhinolaryngology procedures.
Method of Introduction	Manual placement under visual guidance.	Manual placement under visual guidance.	Manual placement under visual guidance.	Same.
Mechanism of Action	Suction from user-supplied vacuum pump draws tissue into side-facing cutting window, tissue excised by oscillating cutter.	Suction from user-supplied vacuum pump draws tissue into side-facing cutting window, tissue excised by oscillating cutter.	Suction from user-supplied vacuum pump draws tissue into side-facing cutting window, tissue excised by oscillating cutter.	Same.
Compatibility	User-supplied endoscope, vacuum pump, and sterile irrigant syringe / bag.	User-supplied endoscope, vacuum pump, and sterile irrigant bag.	User-supplied endoscope, vacuum pump, and sterile irrigant syringe / bag.	Same.
Design Features	**Blade Diameter:** 3.3 mm and 4.0 mm	**Blade Diameter:** 3.5 mm and 4.0 mm (RAD 12 & 40 Blades)	**Blade Diameter:** 3.3 mm and 4.0 mm	Blades of similar diameter are offered.
	Distal Tip: Blunt distal tip with side-facing cutting window.	**Distal Tip:** Blunt distal tip with side-facing cutting window.	**Distal Tip:** Blunt distal tip with side-facing cutting window.	Same.
	Internal Irrigation: Irrigant routed within the shaver blade to the cutting window, where it is suctioned through the device, facilitating evacuation of excised tissue.	**Internal Irrigation:** Irrigant routed within the shaver blade to the cutting window, where it is suctioned through the device, facilitating evacuation of excised tissue.	**Internal Irrigation:** Irrigant routed within the shaver blade to the cutting window, where it is suctioned through the device, facilitating evacuation of excised tissue.	Same.

Model Name	**PolypVac Microdebrider** (Primary Predicate)	**Xomed XPS 3000** (Secondary Predicate)	**PolypVac Microdebrider**	**Rationale for Substantial Equivalence**
Device Trade Name	**PolypVac Microdebrider**	**XPS 3000 System**	**PolypVac Microdebrider**	
510(k) Number	**K161101**	**K041413**	**K163247**	
Human Factors	Handle fits in the surgeon's hand. Shaver blade extends forward while vacuum and irrigant connections extend backwards.	Handle fits in the surgeon's hand. Shaver blade extends forward while vacuum and irrigant connections extend backwards.	Handle fits in the surgeon's hand. Shaver blade extends forward while vacuum and irrigant connections extend backwards.	Same.
	Trigger location on side of handle activates and halts the motion of the tissue cutter.	Foot pedal activates and halts the motion of the tissue cutter.	Trigger location on side of handle activates and halts the motion of the tissue cutter.	Both the subject PolypVac Microdebrider and the Xomed XPS 3000 have controls that must be pressed in order to activate oscillation of the tissue cutter.
Materials / Biocompatibility	Biocompatible for its intended use. All contact materials have been evaluated per ISO 10993.	Biocompatible for its intended use. Specific materials not known.	Biocompatible for its intended use. All contact materials have been evaluated per ISO 10993.	Both the subject PolypVac Microdebrider and the Xomed XPS 3000 are biocompatible for their intended use.
Sterility	E-beam radiation (SAL 10^{-6}).	Ethylene Oxide (single-use shaver blades).	E-beam radiation (SAL 10^{-6}).	Both the subject PolypVac Microdebrider and the shaver blades for the Xomed XPS 3000 are supplied sterile.

VII. Performance Data [§807.92(b)]

Results of non-clinical testing demonstrate that the subject PolypVac Microdebrider is safe and effective for its intended use and substantially equivalent to the predicates.

Summary of Nonclinical Testing [§807.92(b)(1)]

Non-clinical testing was conducted to verify / validate the performance of the device and ensure the subject PolypVac Microdebrider functions as intended and meets design specifications. The results demonstrate that the subject PolypVac Microdebrider is substantially equivalent to the predicate device for its intended use and does not raise new issues of safety or effectiveness. Note that the changes presented in this submission have no effect on previously performed packaging validation and biocompatibility validation testing.

Table 2. Performance Testing and Substantial Equivalence Support

Testing Type	Test Description	Results Supporting Substantial Equivalence
Bench Testing	Durability/Functionality Testing – Motor and Shaft	The subject PolypVac Microdebrider passed all functional testing and met all product specification requirements, thereby demonstrating equivalence to the predicate PolypVac device and suitability to the expanded indications for use.
	Dimensional Testing	
	Pull Force Testing – Bond Strength	
	Predicate Comparison - Resection Rate	
Validation Testing	Cadaver Simulated Use Testing	Simulated use testing was completed successfully, no adverse events were observed. This testing demonstrates that the subject PolypVac Microdebrider is capable of safely performing the following procedures: turbinate reduction / turbinectomy, uncinectomy / maxillary antrostomy, ethmoidectomy, frontal recess dissection, and sphenoidotomy.

Summary of Clinical Data [§807.92(b)(2)]

No clinical testing was performed nor necessary in support of this premarket notification.

VIII. Conclusion [§807.92(b)(3)]

The subject PolypVac Microdebrider has been carefully compared to a legally marketed device with respect to intended use and technological characteristics. In addition, non-clinical testing was conducted to verify / validate the performance of the device and ensure the subject PolypVac Microdebrider functions as intended and meets design specifications. The comparison and non-clinical results demonstrate that the subject PolypVac Microdebrider is substantially equivalent to the primary predicate, the PolypVac Microdebrider (K161101), and the secondary predicate, the Medtronic Xomed XPS 3000 (K041413), for the updated indication described in this submission.