DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 22, 2016

Laurimed LLC
Mr. Brian R. Dubois
Vice President of Engineering
500 Arguello St., Suite 100
Redwood City, CA 94063

Re: K161101
Trade/Device Name: Polypvac Microdebrider (3.3mm And 4.0mm)
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: May 19, 2016
Received: May 23, 2016

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)*
K 161101

Device Name
PolypVac Microdebrider

Indications for Use *(Describe)*
Indicated for the excision of polyps in the nasal passageways and in sinuses for which access has been previously established.

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

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

Name, Address, Phone and Fax Number of Applicant

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Redwood City, CA 94063
Phone: (650) 587-5296
Fax: (650) 587-3823

Contact Person

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Engineering and Manufacturing Manager
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Redwood City, CA 94063
Phone: (650) 587-5296
Fax: (650) 587-3823

Date Prepared

April 18, 2016

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

Trade Name: Laurimed 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 Laurimed PolypVac Microdebrider is substantially equivalent to the Laurimed PolypVac Microdebrider (K133133)

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

The Laurimed PolypVac Microdebrider is intended for cutting and aspirating polyp tissue during sinus and nasal 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)]

Indicated for the excision of polyps in the nasal passageways and in sinuses for which access has been previously established.

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

The technological characteristics and principals of operation of the Laurimed PolypVac Microdebrider are substantially equivalent to the Laurimed PolypVac predicate device (K133133).

Table 1 Summary of Technological Characteristics

Model Name	**PolypVac Microdebrider**	**PolypVac Microdebrider**	**Rationale for Substantial Equivalence**
510(k) Number	**K133133**	**TBD**	
Product Code	ERL	ERL	N/A (Same).
Indications for Use	Indicated for the excision of polyps in the nasal passageways and in sinuses for which access has been previously established.	Indicated for the excision of polyps in the nasal passageways and in sinuses for which access has been previously established.	N/A (Same).
Contraindications	None	None	N/A (Same).
Anatomical Sites	Nose (including accessible sinuses)	Nose (including accessible sinuses)	N/A (Same).
Target Tissue	Sinonasal Polyps	Sinonasal Polyps	N/A (Same).
Equipment / Materials Required	User-supplied endoscope (≤5 mm diameter), vacuum pump, and sterile irrigant syringe / bag.	User-supplied endoscope (≤5 mm diameter), vacuum pump, and sterile irrigant syringe / bag.	N/A (Same).
Method of Introduction	Manual placement under visual guidance.	Manual placement under visual guidance.	N/A (Same).
Mechanism of Action	Suction from user-supplied vacuum pump draws polyp tissue into side-facing cutting window, tissue excised by reciprocating cutter.	Suction from user-supplied vacuum pump draws polyp tissue into side-facing cutting window, tissue excised by reciprocating cutter.	N/A (Same).

Model Name	**PolypVac Microdebrider**	**PolypVac Microdebrider**	**Rationale for Substantial Equivalence**
510(k) Number	**K133133**	**TBD**	
User Interface	The handle body fits in the palm of the surgeon's hand and the shaver blade extends approximately perpendicular to the handle body.	Same. The handle shape has been optimized to reduce size and improve ergonomics.	The modifications to the User Interface do not affect the principles of operation or the performance of the device and no additional risks or hazards have been identified with these changes.
	Rotatable shaver blade (+/- 90^{o}).	Rotatable shaver blade (360^{o}) with knob.	
	Trigger located on side of handle activates and halts reciprocating motion of cutter.	Same. The trigger shape has been optimized.	The modifications to the User Interface do not affect the principles of operation or the performance of the device and no additional risks or hazards have been identified with these changes.
	Connection for vacuum (nipple) located at base of handpiece.	Connection for vacuum located at back of barrel.	
	PVC Tubing with a luer connects to the base of the handpiece.	Smaller diameter tubing with a luer connects at the back of the barrel.	
	Filter integrated into handpiece.	Filter is separate from handpiece.	
Physical / Dimensional Characteristics	Blade diameter: 3.5 mm.	Blade diameter: 3.3 mm & 4.0 mm.	The devices utilize the same technology and principles of operation and the rounded tips are equivalent. No additional risks or hazards have been identified with these changes.
	Rounded atraumatic plastic tip.	Rounded atraumatic metal tip.	
Irrigation	Irrigant is routed to the distal tip through a lumen in the shaver blade's plastic sheath.	Irrigant is routed to the distal tip within the shaver blade (between the evacuation tube and the stainless steel tube).	The modified device meets all fluid flow requirements.
Materials	All contact materials have been evaluated per ISO 10993.	All contact materials have been evaluated per ISO 10993.	Finish product was tested and is biocompatible in accordance with ISO 10993.
Packaging	Package meets ASTM F1980-07 and D4169-14.	Package meets ASTM F1980-07 and D4169-14.	The modified packaging configuration has passed all packaging validation tests, showing that it equivalently protects the device and maintains sterility.
Sterilization	E-beam radiation with SAL 10^{-6}.	E-beam radiation with SAL 10^{-6}.	N/A (Same).

VII. Performance Data [§807.92(b)]

Results of non-clinical testing demonstrated that the Laurimed PolypVac Microdebrider is safe and effective for its intended use and substantially equivalent to the predicate.

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

The Laurimed 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 validate the performance of the device and ensure the Laurimed PolypVac Microdebrider functions as intended and meets design specifications. The comparison and non-clinical results demonstrate that the Laurimed PolypVac Microdebrider is substantially equivalent to the predicate device for its intended use and does not raise new issues of safety or effectiveness.

Table 2. Performance Testing and Substantial Equivalence Support

Testing Type	Test Description	Results Supporting Substantial Equivalence
Bench Testing	Functionality Testing	The modified PolypVac Microdebrider passed all functional testing and met all product specification requirements demonstrating equivalent performance to that of the predicate device.
	Resection Rate	
	Simulated Use Testing	
Biocompatibility Testing	Cytotoxicity	The modified PolypVac Microdebrider and the predicate device are biocompatible in accordance with ISO 10993.
	Sensitization	
	Irritation	

In addition to the performance testing listed in Table 2, Laurimed conducted Shelf-life, Packaging, and Sterilization Validation testing on the Polypvac Microdebrider.

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

No clinical testing was performed or necessary in support of this premarket notification.

VIII. Conclusion [§807.92(b)(3)]

The Laurimed PolypVac Microdebrider does not raise any new issues of safety or effectiveness, as both the modified and the predicate devices have the same intended use, and utilize similar performance specifications and comparable technological features to achieve the same mechanism of action: therefore, the Laurimed PolypVac Microdebrider is substantially equivalent to the predicate devices.