DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 4, 2017

Entellus Medical, Inc.
Ms. Karen E. Peterson
Vice President, Clinical, Regulatory and Quality
3600 Holly Lane North, Suite 40
Plymouth, MN 55447

Re: K163509/S002
Trade/Device Name: XprESS ENT Dilation System
Regulation Number: 21 CFR 874.4420
Regulation Name: Eustachian Tube Balloon Dilation Device
Regulatory Class: Class II
Product Code: PNZ, LRC
Dated: March 7, 2017
Received: March 9, 2017

Dear Ms. Peterson:

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,

Eric A. Mann -S

for Malvina 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)*
K163509

Device Name
XprESS ENT Dilation System

Indications for Use *(Describe)*
To access and treat the maxillary ostia/ethmoid infundibula in patients 2 years and older, and frontal ostia/recesses and sphenoid sinus ostia in patients 12 years and older using a transnasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures.

To dilate the cartilaginous portion of the Eustachian tube for treating persistent Eustachian tube dysfunction in patients 18 years and older using a transnasal approach.

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

Date Prepared: April 5 2017

Submitter Information:
Entellus Medical, Inc.
3600 Holly Lane North, Suite 40
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Establishment Registration: 3006345872

Contact Information:
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Device Information:

Trade Name: XprESS ENT Dilation System

Sinus Dilation

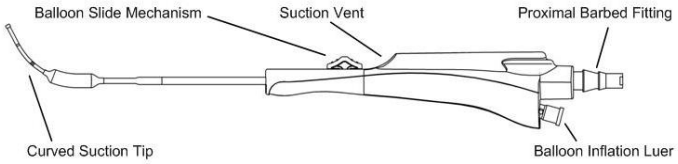
Common Name: Balloon Sinus Dilation System
Classification Name: ENT Manual Surgical Instrument
Product Code: LRC
Regulation Number: Class I, 21 CFR 874.4420

Eustachian Tube Dilation

Common Name: Balloon Eustachian Tube Dilation System
Classification Name: Eustachian Tube Balloon Dilation Device
Product Code: PNZ
Regulation Number: Class II, 21 CFR 874.4180

Predicate Devices: XprESS Multi-Sinus Dilation System [K152434]
Aera Eustachian Tube Balloon Dilation System [DEN150056]

Device Description:
The XprESS ENT Dilation System is intended to remodel or recreate the sinus outflow tract and dilate the Eustachian tube by transnasal balloon dilation. The XprESS device combines features of a curved suction tip and an ostium seeker with the tissue expansion effect of balloon dilation. The familiar features of this device enable a physician to track the device into the sinuses and Eustachian tubes using endoscopic visualization. Since the distal end of the device is re-shapeable, one balloon can be modified to work on multiple sinuses and Eustachian tubes within the same patient.



XprESS ENT Dilation Device

The XprESS device curved suction tip has an atraumatic ball tip. A suction tube may be connected to the proximal barbed fitting to provide active suction by covering the suction vent. An Extension Line connected to a syringe may be connected to the proximal barbed fitting to provide irrigation. The device was designed to prevent fluid from exiting the suction vent during irrigation. The XprESS ENT Dilation System is provided sterile and for single use only.

The Xpress ENT Dilation System includes the XprESS device, Inflation Syringe, Bending Tool, and two Extension Lines. The XprESS LoProfile and Ultra ENT Dilation Systems also include the PathAssist LED Light Fiber. The XprESS Pro ENT Dilation System also includes a Tuohy Adapter.

XprESS is available in the following suction tip sizes and balloon sizes. All suction tips and balloon lengths are appropriate for treating all sinuses and Eustachian tubes; selection is based on physician preference. If treating only Eustachian tubes, the longer length balloons may be more efficient.

XprESS Pro	XprESS LoProfile	XprESS Ultra
Standard Suction Tip (2 mm ball tip, 1 mm ID, 1.5 mm OD)	**LoProfile Suction Tip** (1.75 mm ball tip, 0.7 mm ID, 1.2 mm OD)	**Ultra Suction Tip** (1.5 mm ball tip, 0.5 mm ID, 1.0 mm OD)
Balloon Diameter x Length (mm)	**Balloon Diameter x Length (mm)**	**Balloon Diameter x Length (mm)**
NA	5 x 8	5 x 8
NA	5 x 20	5 x 20
6 x 8	6 x 8	6 x 8
6 x 18	6 x 20	6 x 20
7 x 18	7 x 20	NA

The XprESS ENT Dilation System has been tested to withstand multiple inflations and device tip manipulations in a surgical case.

Indication for Use:
To access and treat the maxillary ostia/ethmoid infundibula in patients 2 years and older, and frontal ostia/recesses and sphenoid sinus ostia in patients 12 years and older using a transnasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures.

To dilate the cartilaginous portion of the Eustachian tube for treating persistent Eustachian tube dysfunction in patients 18 years and older using a transnasal approach.

Contraindications:
None known.

Warnings:
- Do not use XprESS to dilate Eustachian tubes in patients with a history of patulous Eustachian tubes.
- Due to the variability of anatomy, review appropriate radiographic imaging (eg, a CT scan) prior to treatment. Do not use the XprESS device to treat patients with evidence of internal carotid artery dehiscence.

Technological Characteristics:
The XprESS device has expanded indications for use, similar intended use, and identical scientific technology (i.e., principle of operation, design, function, materials, biocompatibility, packaging, shelf life, and sterilization) as the predicate XprESS device [K152434].

The XprESS device has the same expanded indications for use and intended use, and similar scientific technology as the predicate Aera device [DEN150056].

Substantial Equivalence:
The XprESS device has the same indications for use, intended use, and fundamental scientific technology as the predicate devices. The XprESS device is substantially equivalent to the predicate devices.

Performance Data:
Performance testing of the XprESS device consisted of clinical testing to support the expanded indications for use. A prospective, multicenter, randomized controlled trial, comparing XprESS balloon dilation vs control (continued medical therapy) for patients with Eustachian tube dysfunction (ETD) was conducted under IDE G140214. The study included 60 patients diagnosed with ETD for over 12 months, with 3 or more ETD symptoms, and who failed medical therapy. The primary efficacy endpoint was the comparison of mean change in overall Eustachian tube dysfunction questionnaire-7 item (ETDQ-7) score between the XprESS balloon dilation arm and the control arm. The primary safety endpoint was complication rate. The primary efficacy endpoint was met with Eustachian tube balloon dilation demonstrating superiority over medical management for improvement in ETDQ-7 symptom scores ($p<0.0001$). The primary safety endpoint was met with a 0% complication rate. In addition, no adverse events related to the device or the balloon dilation procedure were reported during the study. Performance testing showed that the device performed as intended.

Conclusion:
In conclusion, the technological characteristics are the same as the predicate devices. Performance testing has demonstrated that the device is safe and effective and that its performance is substantially equivalent to the predicate devices.