DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 17, 2014

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

Re: K142252
Trade/Device Name: Xpress Multi-Sinus Dilation Tool
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose, and Throat Manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: September 16, 2014
Received: September 17, 2014

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 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

Indications for Use Statement

Applicant: Entellus Medical, Inc.

510(k) Number (if known): K142252

Device Name: XprESS Multi-Sinus Dilation Tool

Indications for Use

To access and treat the frontal recesses, sphenoid sinus ostia and maxillary ostia/ethmoid infundibula in adults using a trans-nasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures.

Prescription Use____X_____- OR/AND (Part 21 CFR 801 Subpart D)

Over-the-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

510(k) Summary

Date Prepared: August 13, 2014

Submitter Information:
Entellus Medical, Inc.
3600 Holly Lane North, Suite 40
Plymouth, MN 55447

Establishment Registration: 3006345872

Contact Information:
Karen E. Peterson
Vice President Clinical, Regulatory and Quality
(763) 463-7066
kpeterson@entellusmedical.com

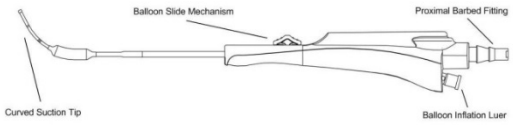
Device Information:

- **Trade Name:** XprESS Multi-Sinus Dilation Tool
- **Common Name:** Sinus Balloon Dilation System
- **Classification Name:** ENT Manual Surgical Instrument
- **Product Code:** LRC
- **Regulation Number:** Class I, 21 CFR 874.4420

Predicate Device: XprESS Multi-Sinus Dilation Tool [K132440]

Device Description:

The XprESS Multi-Sinus Dilation Tool is intended to remodel or recreate the sinus outflow tract via trans-nasal balloon dilation. The XprESS device combines features of a curved suction tip and a frontal ostium seeker with the tissue expansion effect of balloon dilation. The familiar features of this device enable a physician to track the device to the sinus ostium using endoscopic visualization. Since the distal end of the device is re-shapeable, one balloon can be modified to work on multiple sinuses within the same patient.



XprESS Multi-Sinus Dilation Tool

The XprESS 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 Multi-Sinus Dilation Tool is provided sterile and for single use only.

XprESS is available in the following suction tip sizes and balloon sizes. All suction tips and balloon lengths are appropriate for treating all sinuses; selection is based on physician preference.

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

The XprESS Multi-Sinus Dilation Tool has been tested to withstand multiple inflations and device tip manipulations in a surgical case wherein all 6 sinus ostia are being dilated.

Indication for Use:
To access and treat the frontal recesses, sphenoid sinus ostia and maxillary ostia/ethmoid infundibula in adults using a trans-nasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures.

Contraindications:

- Do not use this XprESS device in patients who are allergic to nickel or barium sulfate.
- Do not attach the XprESS device directly to the CT Image Guidance systems. This may result in inaccurate device positioning.

Technological Characteristics:
The XprESS device has the same indications for use and fundamental scientific technology as the predicate device [K132440]. The subject device has the same technological characteristics (i.e., principle of operation, basic design, function, basic materials, biocompatibility, packaging, shelf life and sterilization) as the predicate device.

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

Performance Data:
Performance testing of the XprESS device consisted of biocompatibility, design verification testing, simulated use in a cadaver model, and sterilization to support the additional Ultra suction tip and balloon size. Animal and clinical data was not required for this change. Performance testing showed that the device meets design specifications and performed as intended.

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