



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

November 20, 2015

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

Re: K152434  
Trade/Device Name: XprESS Multi-Sinus Dilation System  
Regulation Number: 21 CFR 874.4420  
Regulation Name: Ear, Nose, and Throat Manual Surgical Instrument  
Regulatory Class: Class I  
Product Code: LRC  
Dated: October 27, 2015  
Received: October 28, 2015

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

510(k) Number (if known)

K152434

Device Name

XprESS Multi-Sinus 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 trans-nasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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.\***

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## 510(k) Summary

**Date Prepared:** August 26, 2015  
**Submitter Information:** Entellus Medical, Inc.  
3600 Holly Lane North, Suite 40  
Plymouth, MN 55447

**Establishment Registration:** 3006345872

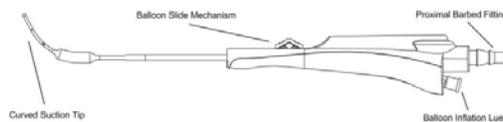
**Contact Information:** Karen E. Peterson  
Vice President Clinical, Regulatory and Quality  
(763) 463-7066  
[kpeterson@entellusmedical.com](mailto:kpeterson@entellusmedical.com)

**Device Information:**  
**Trade Name:** XprESS Multi-Sinus Dilation System  
**Common Name:** Balloon Sinus 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 System [K142252]

### Device Description:

The XprESS Multi-Sinus Dilation System 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 Device

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 System is provided sterile and for single use only.

The Xpress Multi-Sinus Dilation System includes the XprESS device, Inflation Syringe, Bending Tool and two Extension Lines. The XprESS LoProfile and Ultra Multi-Sinus Dilation Systems also include the PathAssist LED Light Fiber. The XprESS Pro Multi-Sinus 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; selection is based on physician preference.

<b>XprESS Pro</b>	<b>XprESS LoProfile</b>	<b>XprESS Ultra</b>
<b>Standard Suction Tip</b> (2mm ball tip, 1mm ID, 1.5mm OD)	<b>LoProfile Suction Tip</b> (1.75mm ball tip, 0.7mm ID, .2mm OD)	<b>Ultra Suction Tip</b> (1.5mm ball tip, 0.5mm ID, 1.0mm OD)
<b>Balloon Diameter x Length (mm)</b>	<b>Balloon Diameter x Length (mm)</b>	<b>Balloon Diameter x Length (mm)</b>
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 System 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 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 trans-nasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures.

**Contraindications:**

None known.

**Technological Characteristics:**

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

**Substantial Equivalence:**

The XprESS device has expanded indications for use, identical intended use, and identical 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 clinical testing to support the expanded indications for use. A prospective, multicenter, single-arm study investigating the use of XprESS in patients aged 2-21 years was conducted in the United States under IDE G140080. The primary outcome measures were procedural technical success rate and complication rate. A total of 157 sinus dilations were attempted in 50 subjects. All 157 attempts were successfully completed for an overall XprESS technical success rate of 100%. No complications (0%) were reported during the study. 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 identical 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.