K102003

510(k) Summary

OCT 22 2010

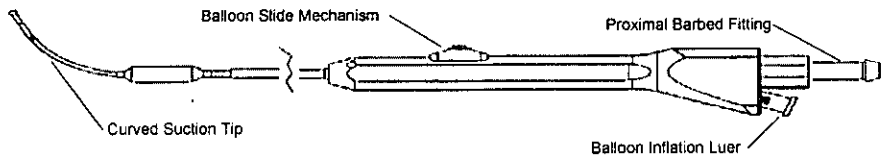
Date Prepared:	September 20, 2010
Submitter Information:	Entellus Medical, Inc. 6705 Wedgwood Court, North Maple Grove, MN 55311
Establishment Registration:	3006345872
Contact Information:	Karen E. Peterson Vice President Clinical, Regulatory and Quality (763) 463-7066 kpeterson@entellusmedical.com
Device 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 Devices:
XprESS Multi-Sinus Dilation Tool [K093007 (Entellus Medical Balloon Device)]
FinESS Sinus Treatment System [K081542]

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.

The XprESS Multi-Sinus Dilation Tool has been tested to withstand multiple inflations and device tip manipulations (up to 25) in a surgical case wherein all 6 sinus ostia are being dilated.

The XprESS device curved suction tip has a 2 mm atraumatic ball tip with a 1 mm inside diameter. A suction tube may be connected to the proximal barbed fitting to provide active suction.



XprESS Multi-Sinus Dilation Tool

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

The items packaged with the Xpress Multi-Sinus Dilation Tool include the Inflation Device and the Infusion Line.

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 device has identical technological characteristics (i.e., design, materials, chemical composition, function, mode of operation, packaging and sterilization) as the predicate device [K093007]. Both devices are sterilized using Ethylene Oxide (EtO), are validated per ISO 11135-1, and have a Sterility Assurance Level (SAL) of 10^{-6}. Both devices are for single use only. Items packaged with both devices include an inflation device and an infusion line. Both devices are biocompatible per ISO 10993-1.

Substantial Equivalence:
No design modifications were necessary to support the expanded indications for use; therefore this device is identical to the currently marketed XprESS device [K093007] in terms of technological characteristics including: the materials, design, function, packaging and sterilization. The intended use of the device is the same as the intended use of the predicate devices. The expanded indication for use in the maxillary sinus is similar to the FinESS Sinus Treatment System [K081542].

Performance Data:
Performance testing of the XprESS device consisted of design verification testing and a cadaver study. Design verification testing included testing for additional balloon inflations and device tip manipulations. A cadaver study was conducted to support the utility of this device in the maxillary sinus. Biocompatibility, sterilization, packaging, distribution, shelf life testing, animal and clinical data were not submitted. Performance testing showed that the device meets design specifications and performed as intended.

Conclusion
In conclusion, the device is substantially equivalent based on a comparison of intended use, indications for use, and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Entellus Medical,Inc.
c/o Ms. Karen Peterson
Vice President Clinical, Regulatory and Quality
6705 Wedgwood Court North
Maple Grove, MN 55311

OCT 2 2 2010

Re: K102003
Trade/Device Name: XprESS Multi-Sinus Dilation Tool (JD-100)
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose & Throat Manual surgical instrument
Regulatory Class: Class I
Product Code: LRC
Dated: August 27, 2010
Received: August 30, 2010

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102003

Indications for Use Statement

510(k) Number: **K102003**

Device Name: **XprESS Multi-Sinus Dilation Tool**

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Prescription Use ____X____ (21 CFR 801 Subpart D) AND/OR 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)

Susan Rudy CRNP

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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