K072302

510(k) Summary

APR - 8 2008

Administrative Information

Name and address

Sponsor:
Entellus Medical, Inc.
10200 73rd Ave. N., Suite 122,
Maple Grove, MN 55369
Tel: 1-763-463-1595
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FDA Est. Reg #: 9097639

Submitted on behalf of sponsor by:
Sew-Wah Tay, Ph.D. (Regulatory Consultant)
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Date Prepared: March 13, 2007

Device Name

Trade Name	Entellus Medical RS Series System
Common Name	Trans-antral Sinus Access and Dilation Catheter System
Classification Name	Ear, nose, and throat electric or pneumatic surgical drill
Classification	21 CFR 874.4250 Class II
Product Code	ERL

Indication for use

To access and treat the maxillary sinus ostium and the ethmoid infundibulum in adults with a trans-antral approach. The bony sinus outflow tract is remodeled by balloon displacement of adjacent bone and paranasal sinus structures.

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Device Description

The Entellus Medical RS Series system allows for trans-mucocutaneous access of the sinus, placement of the balloon catheter with endoscopic guidance and the displacement of the tissue and bony structures by balloon catheter dilation.

Substantial Equivalence

The Entellus Medical Series Device System is substantially equivalent to the previously cleared Kyphx Inflatable Bone Tamp (K981251), Diego RF Dissector and Drill System (K034004) and the Acclarent Relieva Sinus Balloon Catheter (K043527).

The Entellus Medical RS Series System (RS Series) has the same Intended Use as its predicate. The RS Series System, like the Kyphx Inflatable Bone Tamp, allows the use of a minimally invasive procedure to displace bony structure via balloon dilation. Like the Relieva Balloon catheter, it uses balloon to dilate inflamed tissue to produce the equivalent outcomes in the sinuses as the Diego RF Dissector and Drill System.

Performance Data

The device performance test data is provided in the 510(k) submission. The performance data demonstrates that the device meets specification, is biocompatible and meets sterility standards. Performance testing included dimensional verification, bench testing, and simulated use testing and showed that the device meets design specification and performed as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2008

Entellus Medical, Inc
c/o Sew-Wah Tay, PhD.
Regulatory Consultant
18555 37th Ave. n
Plymouth, MN 55446

Re: K072302
Trade/Device Name: Entellus Medical RS Series Balloon System
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, nose, and throat manual surgical instrument
Regulatory Class: Class I
Product Code: LRC
Dated: March 10, 2008
Received: March 13, 2008

Dear Dr. Wah:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

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

510(k) Number (if known):___ K072302_____-

Device Name: Entellus Medical RS Series System

Indications for Use

To access and treat the maxillary sinus ostium and the ethmoid infundibulum in adults with a trans-antral approach. The bony sinus outflow tract is remodeled by balloon displacement of adjacent bone and paranasal sinus structures.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use_____X_____- OR/AND Over-the-Counter Use_____

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

510(k) Number K072302