K093007

1. 510(K) SUMMARY

1.1 ADMINISTRATIVE INFORMATION

Company Name and address

Entellus Medical, Inc.
Deborah Neymark
VP Regulatory, Clinical and QA
6705 Wedgwood Court N,
Maple Grove, MN 55311
Tel: 1-763-463-7056
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FEB - 5 2010

FDA Est. Reg #: 3006345872

DATE : FEBRUARY 4, 2010

Device Name

Trade Name	Entellus Medical Balloon Device
Common Name	Sinus Balloon Dilation System
Classification Name	ENT Manual Surgical Instrument
Classification	21CFR 874.4420 Class I
Product Code	LRC

1.2 SUBSTANTIAL EQUIVALENT PREDICATES

The Entellus Medical is substantially equivalent to:

K081542 – FinESS Sinus Treatment System
K061903- Relieva Sinus Balloon Dilatation Catheter
510(k) exempt – Karl Storz Frontal Sinus Ostium Seeker
510(k) exempt – Karl Storz Sphenoid Punch
510(k) exempt – 5F Ferguson or Frazier Suction Tube

The intended use of the device is similar to the predicates. The device, like the predicates is intended to treat sinus diseases with endoscopic visualization.

The basic features and principle of operations of the device are similar to the predicate devices. Any minor differences do not raise new issues of safety, effectiveness, performance, or function.

1.3 INDICATION FOR USE

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

1.4 DEVICE DESCRIPTION

The Entellus Medical Balloon Device is shaped like a sinus ostium seeker, or a curved suction tube, with a dilatation balloon. It is placed trans-nasally under endoscopic guidance. The position of the device may be verified with fluoroscopy. The size of the device lumen is similar to a 5F suction tube and can be used to aspirate thin liquids from the sinus. The device is provided sterile and is available either in the standard model or the shapeable model.

1.5 PERFORMANCE DATA

The device performance bench test data is provided in the 510(k) submission. Testing showed that the device is biocompatible. Sterilization of the device was achieved via ethylene oxide and sterility of the device assured through sterilization validation.

Bench testing showed that the device meets design specification. The device functional tests showed that it performed as intended. Cadaver studies showed that the device can be safely positioned within the sinus structures as intended. Fluoroscopy imaging showed that the device is easily visible using fluoroscopy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Entellus Medical, Inc.
c/o See-Wah Tay, PhD.
Regulatory Consultant
Libra Medical, LLC
18555 37th Ave. N.
Plymouth, MN 55446

FEB - 5 2010

Re: K093007
Trade/Device Name: Entellus Medical Sinus Balloon Device (Model MSB)
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, nose and throat manual surgical instrument
Regulatory Class: Class I
Product Code: LRC
Dated: January 11, 2010
Received: January 14, 2010

Dear Dr. Tay:

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,

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

INDICATION FOR USE STATEMENT

510(k) Number (if known): K093007

Device Name: Entellus Medical Balloon Device

Indications for Use

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Prescription Use ___X____ (Part 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

S. Ruby CRNP

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

Prescription Use X
(Per 21 CFR 801.109)

510(k) Number K093007