K091681

JUL - 8 2009

510(k) Summary

Date Prepared: June 1, 2009

Submitter Information:
Entellus Medical, Inc.
6705 Wedgwood Court, North
Maple Grove, MN 55311

Establishment Registration: 3006345872

Contact Information:
Deborah L. Neymark
V.P. Regulatory Affairs
(763) 463-7056 (phone)
(763) 463-1599 (fax)
dneymark@entellusmedical.com

Device Information:

Trade Name:	FinESS™ Sinus Treatment
Common Name:	Access Sheath
Classification Name:	Ear, nose and throat manual surgical instrument
Product Code:	LRC
Regulation Number:	Class I, 21 CFR 874.4420

Predicate Device: FinESS Sinus Treatment (K073202)

Device Description:

The access sheath component of the FinESS Sinus Treatment System is comprised of a polycarbonate flange that is over-molded on a stainless steel fluted tube which, when mated with the trocar provided in the kit, gains access to the maxillary sinus. Once the trocar is removed, the access sheath allows delivery of the FinESS cannula, endoscope and balloon catheter.

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.

Summary of Non-Clinical Testing:

Non-clinical testing of the modified access sheath included assessments of the outer profile, fit of the trocar to the sheath, as well as tensile and torque strength of the over-molded component. Biocompatibility of the new material (grey polycarbonate) was also completed.

Summary of Clinical Data:

No clinical evaluations were conducted.

Statement of Equivalence:

The modified access sheath is shown to be substantially equivalent to the existing access sheath included in the FinESS Sinus Treatment System based on a comparison of indications for use and device technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 8 2009

Entellus Medical, Inc.
c/o Deborah L. Neymark
V.P. Regulatory Affairs
Clinical Research and Quality
6705 Wedgwood Court North
Maple Grove, MN 55311

Re: K091681
Trade/Device Name: FinESS™ Sinus Treatment
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose and Throat Manual Surgical Instrument
Regulatory Class: I
Product Code: LRC
Dated: June 4, 2009
Received: June 10, 2009

Dear Ms. Neymark:

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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

K091681

Indications for Use Statement

510(k) Number: K091681

Device Name: FinESS™ Sinus Treatment

Indications for Use:

FinESS is indicated 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.

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)

Daniel C. Clapp

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

510(k) Number K091681