K110739

JUN 14 2011

510(k) Summary

Date Prepared: June 13, 2011

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:	Entellus Medical Sinus Guidewire
Common Name:	Sinus Guidewire
Classification Regulation:	21 CFR 874.4420
Classification Name:	ENT Manual Surgical Instrument
Classification Panel:	ENT
Device Classification:	Class I
Product Code:	LRC

Predicate Devices:
NeoMetrics Selectiva™ SB Guidewire [K033321, K013024]
Relieva Vigor™ Sinus Guidewire

Device Description:
Entellus Medical Sinus Guidewire is a 0.035" – compatible guidewire with a flexible angled radiopaque distal tip. It is constructed of nickel titanium alloys, stainless steel, and features a polymer coating.

Indication for Use
To provide a means to access the frontal, sphenoid and maxillary sinuses, for diagnostic and therapeutic procedures in adults aged 18 and over.

Contraindications:
None

Technological Characteristics:
The device has the same technological characteristics (i.e., design, function, materials, biocompatibility, packaging and sterilization) as the predicate device [K033321, K013024]. The device has the same technological characteristics (i.e., design, function, principle of operation, and biocompatibility) as the predicate device (Relieva Vigor Sinus Guidewire). The subject and

predicate devices are all sterilized using Ethylene Oxide (EtO), validated per ISO 11135-1, and have a Sterility Assurance Level (SAL) of 10^{-6}. All devices are for single use only and are biocompatible per ISO 10993-1.

Substantial Equivalence:
The intended use and indications for use of the subject device is the same as the predicate device (Relieva Vigor Sinus Guidewire). The technological characteristics of the subject device are the same as the predicate devices, [K033321, K013024] and/or Relieva Vigor Sinus Guidewire, including: design, function, principle of operation, materials, biocompatibility, packaging and sterilization.

Performance Data:
Performance testing of the Entellus Medical Sinus Guidewire consisted of design verification testing and a cadaver study. Design verification testing included simulated use and compatibility testing. A cadaver study was conducted to support the utility of this device in the sinus spaces. Biocompatibility, sterilization, packaging, 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. The device is safe and effective for its intended use.

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

JUN 14 2011

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

Re: K110739
Trade/Device Name: Entellus Medical Sinus Guidewire
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose and Throat manual surgical instrument
Regulatory Class: Class I
Product Code: LRC
Dated: March 16, 2011
Received: March 17, 2011

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,

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

Indications for Use Statement

510(k) Number (if known): K110739

Device Name: Entellus Medical Sinus Guidewire

Indications for Use

To provide a means to access the frontal, sphenoid and maxillary sinuses, for diagnostic and therapeutic procedures in adults aged 18 and over.

(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_____

Susan Rudy CRNP

(Division Sign-Off)

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

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