FEB 15 2011

510(k) Summary K102366

Submitter's Name, Address, and Date of Submission

Karen E. Peterson
Vice President Clinical, Regulatory and Quality
6705 Wedgwood Court North
Maple Grove, MN 55311
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Submitted: February 15, 2011

Device Name

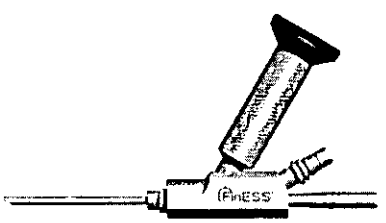
Trade Name:	FinESS Endoscope
Common Name:	Endoscope or Antroscope or Sinuscope
Classification Name:	Nasopharyngoscope (flexible or rigid), 21CFR 874.4760
Product Code:	EOB

Predicate Device

Entellus Medical Flexible Endoscope [K082569] used with Entellus Sinus Cannula [K072302]

Device Description

The FinESS Endoscope is a fiber optic based, manually operated, reusable rigid antroscope designed for performing the FinESS Sinus Treatment procedure. It is short, all metal and fully immersible. It is labeled non-sterile and must be cleaned and disinfected or sterilized prior to use. The endoscope is compatible with standard "B" mount camera couplers, and comes with two light post adapters, which allows the endoscope to be compatible with most commonly used light guides. The endoscope also has a working channel that allows for delivery of the FinESS balloon dilation catheter to treat the maxillary ostium and ethmoid infundibulum.



The FinESS Endoscope is part of and used with the FinESS Sinus Treatment [K081542] and insertion of the endoscope is performed using a sterile access sheath [K091681].

Indications for Use
The FinESS Endoscope is intended to provide a means to visualize the maxillary sinus cavity and deliver the FinESS balloon dilation catheter to treat the maxillary sinus ostium and the ethmoid infundibulum in adults with a trans-antral approach. The endoscope is part of the FinESS Sinus Treatment and is inserted via a sterile access sheath through the canine fossa.

Substantial Equivalence
The FinESS Endoscope has the same intended use, principal of operation, biocompatibility, device and accessory compatibility, reusability, and reprocessing methods as the predicate device.

The FinESS Endoscope has some different technological features compared to the predicate device, however, these differences present the same type of questions about safety or effectiveness, accepted scientific methods exist for evaluating the features, and data are provided to demonstrate that the features have not diminished safety or effectiveness.

Performance Data
The device performance test data is provided in the 510(k) submission. Performance tests included biocompatibility testing, dimensional and functional verification, cadaver studies, manual cleaning validation utilizing total organic carbon as study endpoint, manual high level disinfection validation, sterilization validation of STERRAD NX system (per ISO 14937), compatibility testing, and storage and transportation testing. Animal and clinical data were not submitted. The testing showed that the device meets design specifications and performs as intended.

Conclusion
FinESS Endoscope is substantially equivalent to the predicate device. FinESS Endoscope 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

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

FEB 15 2011

Re: K102366
Trade/Device Name: Entellus FinESS Endoscope (Model ES300)
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOB
Dated: February 11, 2011
Received: February 14, 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.

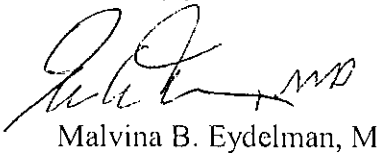
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

Enclosure

Indications for Use Statement

510(k) Number (if known): K102366

Device Name: FinESS Endoscope

Indications for Use

The FinESS Endoscope is intended to provide a means to visualize the maxillary sinus cavity and deliver the FinESS balloon dilation catheter to treat the maxillary sinus ostium and the ethmoid infundibulum in adults with a trans-antral approach. The endoscope is part of the FinESS Sinus Treatment and is inserted via a sterile access sheath through the canine fossa.

(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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