K113522

Entellus Medical

JAN 27 2012

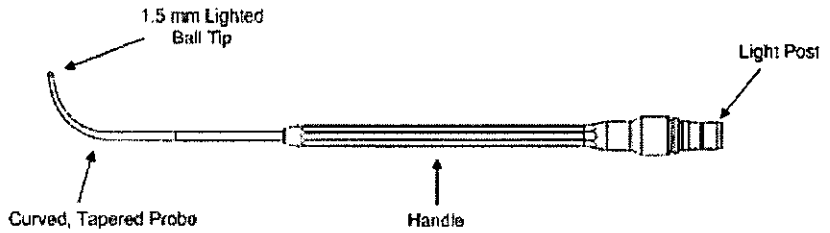
entellus MEDICAL™

510(k) Summary

Date Prepared:	January 23, 2012
Submitter Information:	Entellus Medical, Inc. 6705 Wedgwood Court, North Maple Grove, MN 55311
Establishment Registration:	3006345872
Contact Information:	Garrett P. Ahlborg Regulatory Affairs Specialist (763) 463-7074 gahlborg@entellusmedical.com
Device Information:	
Trade Name:	PathAssist™ Light Seeker™
Common Name:	Illuminating Sinus Seeker
Classification Name:	ENT Manual Surgical Instrument
Product Code:	LRC
Regulation Number:	Class I, 21 CFR 874.4420

Predicate Device:
PathAssist™ Light Seeker™ [K110158]

Device Description:
The PathAssist™ Light Seeker™ is a fiber optic based, manually operated, reusable sinus seeker that can be connected to a light source to emit light from its distal end. It is labeled non-sterile and must be cleaned and sterilized or cleaned and high level disinfected prior to each use. The Light Seeker comes with two standard light post adapters, which allow the device to be compatible with commonly used 2.5mm light guides (cables).



PathAssist™ Light Seeker™

Indications for Use:
The PathAssist Light Seeker is intended to locate, illuminate within, and transilluminate across nasal and sinus structures, including the frontal, ethmoid and maxillary sinuses, in patients aged 18 and over.

Contraindications:
None

Technological Characteristics:
The Light Seeker has the same indications for use and fundamental scientific technology as the predicate device [K110158]. The subject device has the same technological characteristics (i.e., principle of operation, design, function, materials, and biocompatibility per ISO 10993-1) as the predicate device. The reprocessing methods for the subject device have been modified to include the option of high level disinfection, in addition to the previously cleared validated methods for cleaning and sterilization.

Substantial Equivalence:
The Light Seeker has the same indications for use and fundamental scientific technology as the predicate device. The Light Seeker is substantially equivalent to the predicate device.

Performance Data:
Performance testing of the Light Seeker consisted of design verification testing after repetitive reprocessing cycling consisting of manual cleaning and manual high level disinfection. Design verification testing included functional testing to support the useful life of the device. High level disinfection validation results obtained from device [K102366] were submitted. Cleaning validation results obtained from device [K102366] and sterilization validation data were submitted and cleared for the subject device in [K110158]. Biocompatibility, packaging testing, animal and clinical data was not submitted. Performance testing showed that the subject device meets design specifications and performs as intended.

Conclusion:
In conclusion, the indications for use and technological characteristics are the same as or equivalent to the predicate device. Performance testing has demonstrated that the device is safe and effective and that its performance is substantially equivalent to the predicate device.

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 Garrett P. Ahlborg
Regulatory Affairs Specialist
6705 Wedgwood Court North
Maple Grove, MN 55311

JAN 27 2012

Re: K113522
Trade/Device Name: PathAssist™ Light Seeker™
Regulation Number: 21 CFR 874.4420
Regulation Name: ENT Manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: December 28, 2011
Received: December 29, 2011

Dear Mr. Ahlborg:

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

510(k) Number (if known): K113522

Device Name: PathAssist™ Light Seeker™

Indications For Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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