K110158

JUN - 7 2011

510(k) Summary

Date Prepared: May 10, 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
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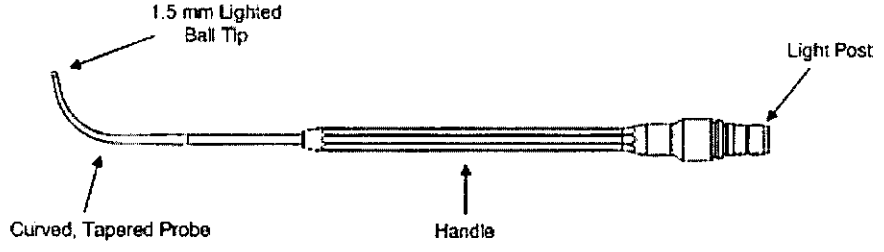
Device Information:

Trade Name:	PathAssist Light Seeker
Common Name:	Sinus Seeker
Classification Name:	ENT Manual Surgical Instrument
Product Code:	LRC
Regulation Number:	Class I, 21 CFR 874.4420

Predicate Devices:
Sinus Seekers – Surgical Instrument – [510(k) exempt]
Relieva Luma™ Sinus Illumination System [K071845]

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 prior to each use. The PathAssist 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

Indication 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 adults aged 18 and over.

Contraindications:
None

Technological Characteristics:
The subject device has the same technological characteristics (i.e., principle of operation, design, function, materials, biocompatibility, reusability and reprocessing methods) as the predicate devices: [Sinus Seekers, 510(k) exempt] and/or [Relieva Luma Sinus Illumination System, K093007].

Both the subject device and predicate device [Sinus Seekers, 510(k) exempt] are shaped like a sinus seeker and are advanced under endoscopic visualization into the sinus, are made of stainless steel, are provided non-sterile, are reusable, and must be cleaned and sterilized between each use. Both devices are biocompatible per ISO 10993-1.

Both the subject device and predicate device [Relieva Luma Sinus Illumination System, K071845] transmit light from the proximal to distal tip of the device via light fibers that can be seen via transillumination. Both devices can be connected to a standard light source via a light cable and an adapter. Both devices are biocompatible per ISO 10993-1.

Substantial Equivalence:
The intended use and indications for use of the subject device is the same as the intended use and indications for use of the predicate device [Relieva Luma Sinus Illumination System, K093007]. The technological characteristics of the subject device are the same as the predicate devices, [Sinus Seekers, 510(k) exempt] and/or [Relieva Luma Sinus Illumination System, K093007], including: principle of operation, design, function, materials, biocompatibility, reusability and reprocessing methods.

Performance Data:
Performance testing of the device consisted of biocompatibility testing, design verification testing, simulated use design validation testing in a cadaver model, steam sterilization validation, compatibility testing, and storage and transportation testing. Design verification testing included dimensional and functional testing to support the useful life of the device. Cleaning validation testing performed on device [K102366] was submitted. Animal and clinical data were not submitted. Performance testing showed that the device meets design specifications and performs 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

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

JUN - 7 2011

Re: K110158
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: May 12, 2011
Received: May 13, 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): K110158

Device Name: 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 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

510(k) Number K110158