K130503

JUN 1 1 2013

510(k) Summary

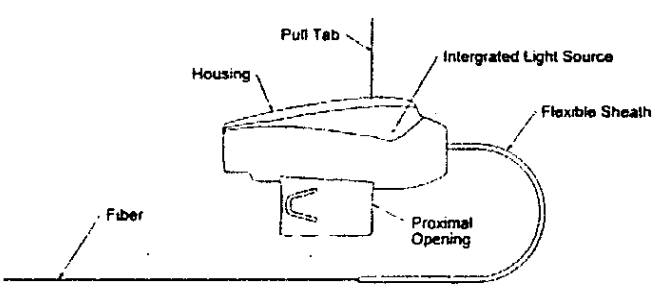
Date Prepared:	February 26, 2013
Submitter Information:	Entellus Medical, Inc. 3600 Holly lane North, Suite 40 Plymouth, MN 55447
Establishment Registration:	3006345872
Contact Information:	Karen E. Peterson Vice President Clinical, Regulatory and Quality (763) 463-7066 kpeterson@entellusmedical.com

Device Information:

Trade Name:	PathAssist LED Light Fiber
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:
PathAssist Light Fiber [K120962]
"PLS" Portable Light Source [K091829]

Device Description:
The PathAssist LED Light Fiber is a flexible instrument that emits light from the distal end. The LED Light Fiber is provided sterile and is for single use only. The device consists of a flexible illumination fiber, a protective sheath and an integrated battery powered LED light source. When the LED Light Fiber is activated the fiber will emit red light from the distal tip for over 60 minutes. It has a fiber nominal working length of 27.6cm with an outer diameter of 0.5mm (0.020").



PathAssist LED Light Fiber

Indication for Use
To locate, illuminate within, and transilluminate across nasal and sinus structures in patients aged 18 and over.

The intended use of the subject device is the same as the predicate devices: PathAssist Light Fiber [K120962] and "PLS" Portable Light Source [K091829], and the indications for use of the subject device is the same as the predicate device [K120962].

Contraindications:
None

Technological Characteristics:
The subject device has the same technological characteristics (i.e., principle of operation, design, function, materials, biocompatibility, shelf life, packaging, sterilization and energy source) as the predicate devices: PathAssist Light Fiber [K120962] and/or "PLS" Portable Light Source [K091829].

Both the subject device and predicate device [K120962] are flexible devices that transmit light from the proximal to distal tip of the device via a light fiber that can be seen via transillumination. Both devices are sterilized using Ethylene Oxide (EtO) and validated per ISO 11135-1, and have a Sterility Assurance Level (SAL) of 10^{-6}. Both devices are provided sterile, are for single use only and are biocompatible per ISO 10993-1. The subject device has an internal light source whereas the predicate device [K120962] must be connected to a light source.

Both the subject device and the predicate device [K091829] incorporate an internal battery operated LED light source. Both devices have undergone EMC and electrical safety testing per IEC 60601-1, IEC 60601-2-18 and IEC 60601-1-2. The subject device is provided sterile and is for single use only whereas the predicate device is provided non-sterile and must be cleaned and high level disinfected between each use.

Substantial Equivalence:
The intended use of the subject device is the same as the predicate devices [K120962] and [K091829] and the indications for use is the same as the predicate device [K120962]. The technological characteristics of the subject device are the same as the predicate device [K120962] and/or predicate device [K091829], including: principle of operation, design, function, materials, biocompatibility, shelf life, packaging, sterilization and energy source.

Performance Data:
Performance testing of the PathAssist LED Light Fiber consisted of EMC and electrical safety, design verification (functional, mechanical, and compatibility testing), packaging, shelf life, and simulated use in a cadaver model. Biocompatibility testing and sterilization validation was referenced. 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 Center – WO66-G609
Silver Spring, MD 20993-002

June 11, 2013

Entellus Medical, Inc.
Karen E. Peterson
Vice President Clinical, Regulatory and Quality
3600 Holly lane North, Suite 40
Plymouth, MN 55447

Re: K130503
Trade Name: PathAssist LED Light Fiber
Regulation Number: 21 CFR 874.4420
Regulation Name: ENT Manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: February 26, 2013
Received: February 28, 2013

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,

Eric A. Mann -S

for Malvina B. Eydelman, MD
Director
Division of Ophthalmic and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

6. Indications for Use Statement

510(k) Number (if known): K 130 503

Device Name: PathAssist LED Light Fiber

Indications for Use

To locate, illuminate within, and transilluminate across nasal and sinus structures in patients 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_____

Eric A. Mann -S