DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 20, 2015

Entellus Medical, Inc.
Ms. Karen Peterson
Vice President, Clinical, Regulatory And Quality
3600 Holly Lane North, Suite 40
Plymouth, MN 55447

Re: K152435
Trade/Device Name: PathAssist LED Light Fiber
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose, and Throat Manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: October 29, 2015
Received: October 30, 2015

Dear Karen 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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152435

Device Name
PathAssist LED Light Fiber

Indications for Use *(Describe)*
To locate, illuminate within, and transilluminate across nasal and sinus structures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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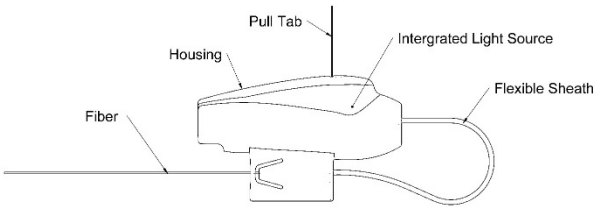
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Prepared:	August 26, 2015
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 Name:	ENT Manual Surgical Instrument
Product Code:	LRC
Regulation Number:	Class I, 21 CFR 874.4420
Predicate Device:	PathAssist LED Light Fiber [K141916]

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 0.375mm (0.015").

The PathAssist LED Light Fiber is packaged alone or may be packaged with XprESS (LoProfile or Ultra).



PathAssist LED Light Fiber

Indication for Use:
To locate, illuminate within, and transilluminate across nasal and sinus structures.

Contraindications:
None known.

Technological Characteristics:
The LED Light Fiber has expanded indications for use, identical intended use, and identical scientific technology (i.e., principle of operation, design, function, materials, biocompatibility, packaging, shelf life, and sterilization) as the predicate device.

Substantial Equivalence:
The LED Light Fiber has expanded indications for use, identical intended use, and identical fundamental scientific technology as the predicate device. The LED Light Fiber is substantially equivalent to the predicate device.

Performance Data:
Performance testing of the LED Light Fiber consisted of clinical testing to support the expanded indications for use. A prospective, multicenter, single-arm study investigating the use of LED Light Fiber in patients aged 2-21 years was conducted in the United States under IDE G140080. The primary outcome measures were procedural technical success rate and complication rate. A total of 129 sinus illuminations/transilluminations were attempted in 50 subjects. A total of 127 attempts were successfully completed for an overall LED Light Fiber technical success rate of 98.4%. No complications (0%) were reported during the study. In addition, no adverse events related to the device or the device procedure were reported during the study. Performance testing showed that the device performed as intended.

Conclusion:
In conclusion, the technological characteristics are identical 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.