510(k) Summary
K082569

SEP 1 8 2008

Date Prepared: September 17, 2008

Submitted By:

Company: Entellus Medical, Inc.
Address: 6705 Wedgwood Court North
Maple Grove, MN 55311
Establishment Reg: Not Yet Assigned
Owner/Operator #: 10025424
Contact Person: Deborah Neymark
V.P., Regulatory Affairs, Clinical Research and Quality
763-463-7056 (phone)
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Device Information:

Trade Name: Entellus Medical Flexible Endoscope and Eyepiece
Common Name: Flexible Endoscope
Classification Name: Nasopharyngoscope (flexible and rigid)
Classification: 21 CFR 874.4760
Product Code: EOB

Predicate Device:

The Entellus Medical Flexible Endoscope and Eyepiece is substantially equivalent to the following devices:

- Karl Storz Miniature Endoscope (K070752)
- Karl Storz Video Rhino-Laryngoscope System (K072387)
- Vision-Sciences Trans-Nasal Esophagoscope with Endosheath System (K031786)

Device Description:

The Entellus Medical Flexible Endoscope and Eyepiece consist of a flexible fiber optic scope and eyepiece that is compatible with most commercially available endoscopic video systems.

Indications for Use:

The Entellus Flexible Endoscope and Eyepiece is intended to visualize the internal cavities of the ear, airways, nose and sinus cavities during diagnostic and therapeutic endoscope procedures. The device can be used with compatible video systems.

Performance Data:

The device performance test data is provided in the 510(k) submission included biocompatibility testing, dimensional verification, bench testing, and qualification of reprocessing procedures. The performance data demonstrates that the device meets its established specifications, is biocompatible, and is able to perform as intended following standard reprocessing procedures.

Conclusion:

The Entellus Medical Flexible Endoscope and Eyepiece is substantially equivalent to the identified predicate device based on a comparison of the indications for use, the technological characteristics of the device and an assessment of the submitted performance data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 8 2008

Entellus Medical Inc.
c/o Mark Job
Regulatory Technology Services
1394 25th Street, NW
Buffalo, MN 55313

Re: K082569
Trade/Device Name: Entellus Medical Flexible Endoscope and Eyepiece
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible and rigid)
Regulatory Class: Class II
Product Code: EOB
Dated: September 4, 2008
Received: September 5, 2008

Dear Mr. Job:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

K082569

Indications for Use Statement

510(k) Number: K082569

Device Name: Entellus Medical Flexible Endoscope and Eyepiece

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K082569

Prescription Use X
(Per 21 CFR 801.109)