K080622

510(k) SUMMARY

OPTIM's ENTity NasoView LED Nasopharyngoscope

APR - 2 2008

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

OPTIM Incorporated

64 Technology Park Road
Sturbridge, MA 01566-1253

Phone: (508) 347-5100
Facsimile: (508) 347-2380

Contact Person: Robert Krupa

Date Prepared: March 5, 2008

Name of Device and Name/Address of Sponsor

ENTity NasoView LED Nasopharyngoscope

OPTIM, Incorporated
64 Technology Park Road
Sturbridge, MA 01566-1253

Common or Usual Name

Nasopharyngoscope

Classification Name and Product Code

Nasopharyngoscope; EOB

Predicate Devices

OL-1 Airway Fiberscope, K864821
Vision-Sciences EF100 nasopharyngoscope, K942265
Vision-Sciences ENT-3000 nasopharyngoscope, K050972
Vision-Sciences ENT-5000 nasopharyngoscope, K072073

Purpose of the Special 510(k) Notice

The ENTity NasoView is a modification of the OL-1 Airway Fiberscope.

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Intended Use / Indications for Use

For oral or nasal introduction for the examination of the upper airway from the nasal passage to the vocal cords.

Technological Characteristics

The ENTity NasoView is a modification of the OL-1 Airway Fiberscope. The device has been modified to include a battery-operated LED light source internal to the device control body. An accessory charger is provided for charging the battery outside the scope.

Performance Data

In support of this Special 510(k), OPTIM has certified compliance with 21 CFR § 820.30, Design Control Requirements, including a risk analysis assessment. Verification and validation activities have been completed for the device modifications.

Substantial Equivalence

ENTity NasoView has the same intended use and indications for use, and similar technological characteristics and principles of operation, as the predicates. The modifications incorporated in the ENTity NasoView do not raise any new questions of safety or effectiveness. Validation and verification testing demonstrates that the ENTity NasoView is as safe and effective as the predicate devices. Thus, the ENTity NasoView is substantially equivalent to legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2008

OPTIM Incorporated
c/o Robert Krupa
64 Technology Park Road
Sturbridge, MA 01566-1253

Re: K080622
Trade/Device Name: ENTity NasoView LED Nasopharyngoscope
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOB
Dated: March 5, 2008
Received: March 5, 2008

Dear Dr. Krupa:

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

K080622

Indications for Use Statement

510(k) Number (if known): K080622

Device Name: OPTIM's ENTity NasoView LED Nasopharyngoscope

Indications for Use: For oral or nasal introduction for the examination of the upper airway from the nasal passage to the vocal cords.

Prescription Use X AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 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 K080622