K091829

510(k) SUMMARY

OPTIM's "PLS" Portable Light Source

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

JUL 28 2009

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

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Contact Person: Robert Krupa

Date Prepared: June 19, 2009

Name of Device and Name/Address of Sponsor

"PLS" Portable Light Source

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

Common or Usual Name

LED Light Source

Classification Name and Product Code

LED Light Source; NTN

Predicate Devices

ENTity NasoView Fiberscope, K080622
SOPRO 225 Dual Halogen Light Source, K072912

Purpose of the Abbreviated 510(k) Notice

The PLS is a modification of the light source embedded into the ENTity NasoView Fiberscope.

Intended Use / Indications for Use

It is intended to provide illumination for examination, diagnostic, and therapeutic applications, particularly in endoscopy.

Technological Characteristics

The PLS is a stand-alone, portable, detachable adaptation of the light source embedded into the ENTity NasoView Fiberscope. The PLS is an accessory to endoscopes and other devices that require an external light source.

Performance Data

In support of this Abbreviated 510(k), OPTIM has provided a declaration of conformity to IEC Medical Electrical Equipment standards 60601-1:1998, 60601-2-18:1996, and 60601-1-2:2001.

Substantial Equivalence

The PLS has the same intended use and fundamental scientific technology as the light engine embedded into the ENTity NasoView Fiberscope. Performance testing demonstrates that the PLS is as safe and as effective as the predicate device. The PLS also has the same intended us as the SOPRO 225 Dual Halogen Light Source. Thus, the PLS 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

OPTIM, Inc.
% Robert J. Krupa, Ph.D.
Chief Scientist
64 Technology Park Road
Sturbridge, Massachusetts 01566-1262

JUL 2 8 2009

Re: K091829
Trade/Device Name: OPTIM's "PLS" Portable Light Source
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NTN
Dated: June 19, 2009
Received: June 19, 2009

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):_____

Device Name: OPTIM's "PLS" Portable Light Source

Indications for Use: To provide illumination for examination, diagnostic, and therapeutic applications, particularly in endoscopy.

Prescription Use __X__ (Per 21 C.F.R. 801.109) AND/OR Over-The-Counter Use____ (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 Surgical, Orthopedic, and Restorative Devices

510(k) Number K091829