K093792

510 (k) Summary of Safety and Effectiveness Statement

Device Name:

Proprietary Name:	LED Light Source (LLS-050 LED Illuminator)
Common and Usual Name:	Light Source, Illuminator
Classification Name:	Light Source, Fiberoptic, Routine, CFR 21 § 876.1500

Manufacturer Information:

Sunoptic Technologies®, LLC
6018 Bowdendale Avenue
Jacksonville, FL 32216 USA

MAR 18 2010

Establishment Registration Number: 1035968

FDA Device Classification

Device Description:	Gastroenterology - Endoscope and Accessories
Medical Specialty:	General and Plastic Surgery
Product Code:	FCW
510(k) Exempt?	No
Regulation Number:	876.1500

Product Description:

Indications for Use: The LED Light Source is used to illuminate the site of surgery during minimally invasive surgical procedures in arthroscopy (orthopedic surgery), laparoscopy (general and gynecological surgery) and in Endoscopy (general, gastroenterological and ENT surgery. The light is transmitted from the light source through a fiber optic cable and a scope.

Voluntary Safety and Performance Standards: The LED Light Source will conform to the Medical Safety Stds.: UL60601-1,CAN/CSA C22.2 No.601.1 (SUP1+AM2), Medical EMC Stds. EN 60601-1-2 and CE marked

Predicate Device:

The LED Light Source is substantially equivalent in terms of safety and effectiveness to currently marketed devices including the predicate device Stryker L9000 LED Light Source (K082813).

Substantial Equivalence

The technological differences between the LED Light Source (LLS-050) and the Stryker LED Light Source (L9000) do not raise new questions of safety or effectiveness. Therefore, the LED Light Source (LLS-050) is substantially equivalent to the predicate marketed device. Refer to section IV for a detailed comparison.

Contact:

Janice G. Lee — 2/24/10

Janice G. Lee **Date**
Sunoptic Technologies®, LLC
6018 Bowdendale Avenue
Jacksonville, FL 32216 USA
904 737 7611 (phone); 904 733 4832 (fax); or e-mail janice.lee@sunoptictech.com.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR 18 2010

Sunoptic Technologies, LLC
% Ms. Janice G. Lee
Director, QA & Regulatory Affairs
6018 Bowdendale Avenue
Jacksonville, Florida 32216-6042

Re: K093792
Trade/Device Name: LED Light Source
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FCW
Dated: March 15, 2010
Received: March 16, 2010

Dear Ms. Lee:

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,

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

510(k) Number (if known): K093792

Device Name: LED Light Source

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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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