

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

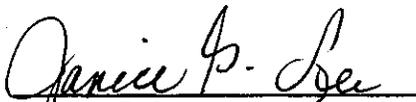
**Predicate Device:**

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

  
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](mailto:janice.lee@sunoptictech.com).

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Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
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.

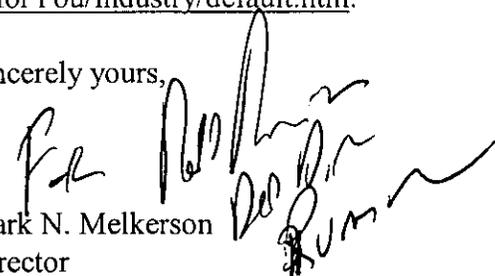
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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" (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 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

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.

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)

Michael J. Forman  
Concurrence of CDRH, Office of Device Evaluation (ODE)  
(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

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