

K102167

### 510(k) Summary of Safety and Effectiveness Statement

AUG 17 2010

**Device Name:**

**Proprietary Name:** LO-50 LED Light Source  
**Common and Usual Name:** Light Source, Illuminator  
**Classification Name:** Light Source, Fiberoptic, Routine, CFR 21 §876.1500

**Manufacturer Information:**

Fiberoptics Technology, Inc.  
 1 Quassett Road  
 Pomfret, CT 06258  
 USA

Establishment Registration Number: 1222275

**FDA Device Classification**

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

**Product Description:** The LO-50 LED Light Source is a fiber optic light source using a single solid state light emitting element to produce visible light required to illuminate surgical sites for direct or indirect visualization during medical procedures. The LED produces white light by electroluminescence, rather than incandescence (as in a tungsten filament lamp) or fluorescence (as in a xenon lamp.) Both of the latter technologies use large amounts of electricity and generate significant heat in creating light. LED generates a greater light output as a percentage of energy input to the lamp. It uses Pulse Width Modulation to control the on/off time of the LED at full output to determine brightness. The LO-50 light source uses a small optical element to capture and direct the light to a port into which one of many common medical light guides may be fitted to conduct the light where needed. The unit consists of the aforementioned LED, cooling fan, light port, sheet metal covers, plastic front and rear covers, and front mounted power switch and dimming control. The unit is very similar in design, format, functionality and size to other light sources including the predicate device.

**Indications for Use:** The LO-50 LED Light Source is intended to provide light via an accessory fiber optic light guide to illuminate the site of surgery during minimally invasive surgical procedures in arthroscopy (orthopedic surgery), and for use with a headlight for general surgical or examination procedures.

**Voluntary Safety and Performance Standards:** The LO-50 LED Light Source conforms to the following Medical Device Safety Standards: UL60601-1, CAN/CSA 22.2 No. 601.1. The LO-50 LED Light Source conforms to the Medical Device EMC Standard EN60601-1-2.

**Predicate Device:**

The LO-50 LED Light Source is substantially equivalent in terms of safety and effectiveness to the currently marketed predicate device: Sunoptics Technologies LLS-050 LED Light Source (K093792).

**Performance and Safety Comparison to Predicate Device:**

Both light sources were non-clinically tested to determine the safety and efficacy under the indications for use. The units were tested for operation, user interface, light quality and brightness and safety during use. User controls and operations were examine and compared, as well as ease of connection and disconnection of common light guides. The brightness of light emitted by a reference light guide from each unit was measured. Brightness and quality of illumination from a typical fiber optic headlight system and arthroscope was examined and compared. Operating temperatures of the light sources, accessible parts and lighted instruments were measured and compared. Each unit had essentially equivalent performance and temperature characteristics.

**Substantial Equivalence:**

The technological differences between the LO-50 LED Light Source and Sunoptics Technologies LLS-050 LED Light Source do not raise new questions of safety or effectiveness. Both light sources produced equivalent brightness and quality of light, were similar in control and operation, interfaced correctly and effectively to the arthroscope and surgical headlight used to test and verify performance. The LED technology, power supply, user interface and connectivity are nearly identical. Therefore, the LO-50 LED Light Source is substantially equivalent to the predicate marketed device.

Contact:



08/17/10

Allan Guillotte

Date

Fiberoptics Technology, Inc.

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Pomfret, CT 06258

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Fiberoptics Technology, Inc.  
% Regulatory Technology Services, Inc.  
Mr. Mark Job  
1394 25<sup>th</sup> Street, NW  
Buffalo, Minnesota 55313

AUG 17 2010

Re: K102167

Trade/Device Name: LO-50 LED Light Source  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: Class II  
Product Code: NTN, FCW  
Dated: July 30, 2010  
Received: August 02, 2010

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. 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

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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

K102167

### Indications for Use

510(k) Number (if known):

Device Name: LO-50 LED Light Source

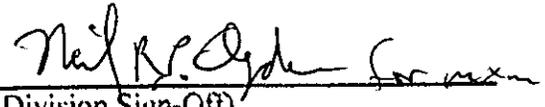
Indications for Use:

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Prescription Use  AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (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 Surgical, Orthopedic,  
and Restorative Devices

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