OCT 5 2007

1. Device Name

Trade Name:	Harmony LED-1 Surgical Lighting System.
Common Name:	Light, Surgical, Ceiling Mounted.
Classification Name:	Light, Surgical, Ceiling Mounted.
Classification Number:	21 CFR 878.4580
Product Code:	FSY

2. Predicate Devices

- POWERLED™ Surgical Light System cleared for market on March 16, 2007 as K070442 (Getinge USA, Inc).
- iLED cleared for market on June 22, 2006 as K061317 (Trumpf Kreuzer Medizin).
- Amsco Harmony Surgical Lighting and Media System cleared for market on December 13, 2001 as K013242 (STERIS Corporation).

3. Device Description

The proposed Harmony LED-1 Surgical Lighting System subjected in this submission is a variable pattern / intensity surgical light designed to provide visible illumination of the surgical field and the patient and to provide video-visual procedural support for the hospital staff during surgical procedures.

The proposed Harmony LED-1 Surgical Lighting System Lighthead is specifically designed to be the next generation lighthead which can be added to the existing center mounted suspension system supporting the horizontal arms, spring arms and yokes of the predicate device Amsco Harmony Surgical Lighting and Media System cleared for market on December 13, 2001 as K013242 (STERIS Corporation). Like the predicate device the system operates via an electronic controller.

The proposed Harmony LED-1 Surgical Lighting System accessories are as follows:

- Ambient Light System.
- IR remote control for camera module.
- DeepSite Fiber Optic Light.
- Fiber Optic Video Enabled Video.
- STERIS ACT Interface.

- Camera Module.
- Dual or Single Flat Panel Monitors.
- CRT.
- 24VDC Battery Backup support.
- Secondary Spindle Mount.
- Low Profile Wall Control Unit.
- Remote Power Module Unit.
- Sterile Disposable Handle Covers.

4. Intended Use

The proposed Harmony LED-1 Surgical Lighting System subjected in this submission is a variable pattern / intensity surgical light designed to provide visible illumination of the surgical field and the patient and to provide video-visual procedural support for the hospital staff during surgical procedures.
The performance of the Harmony LED-1 Surgical Lighting System meets the general requirements for safety as defined in CEI/IEC 60601-1 and IEC 60601-2-41 for Medical Electrical Equipment.

5. Description of Safety and Substantial Equivalence

The proposed Harmony LED-1 Surgical Lighting System, like its predicate devices is a variable pattern, variable intensity surgical light designed to provide visible illumination of the surgical field and the patient and to provide video-visual procedural support for the hospital staff during surgical procedures. The Proposed device, is identical in function, intended use, components, technology, and performance to the predicate devices: AMSCO Harmony LA Surgical Light System (K013242) manufactured and owned by STERIS Corporation and the iLED (K061317) manufactured by Trumpf Kreuzer Medizin Systeme.

The differences between the proposed and predicate devices are limited to differences in design, material, and operational. These differences do not raise any new issues of safety and efficacy.

6. Performance Testing

Performance testing was conducted to verify that the proposed Harmony LED-1 Surgical Lighting System meet the requirements for Medical Electrical Equipment as defined in CEI/IEC 60601-1 and IEC 60601-2-41.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

STERIS Corporation
% Mr. Jack Scoville
Fellow, Regulatory Affairs
5960 Heisley Road
Mentor, Ohio 44060-1834

OCT 5 ˇ 2007

Re: K072072
Trade/Device Name: Harmony LED 1 Surgical Lighting System
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FSY
Dated: September 24, 2007
Received: September 25, 2007

Dear Mr. Scoville:

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.

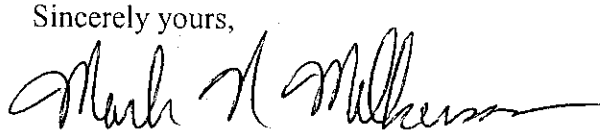
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,



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

Enclosure

Indications for Use

510(k) Number (if known): **K072072**

Device Name: Harmony LED 1 Surgical Lighting System

Indications For Use:

The proposed Harmony LED-1 Surgical lighting System subjected in this submission is a variable pattern/ intensity surgical light designed to provide visible illumination of the surgical field and patient and to provide video-visual procedural support for the hospital staff during surgical procedures.

Mark N Milkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072072

Prescription Use ___X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)