STERIS®

MAR 1 7 2010

K100395

510(k) Summary
For
Harmony vLED Surgical Lighting System

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (216) 354-2600
Fax No: (216) 639-4459

Contact: Robert F. Sullivan
Senior Director, Regulatory Affairs

Telephone: 440 392 7695
Fax No: 440 357 9198

Submission Date: February 12, 2010

1. Device Name

Trade Name:	Harmony vLED 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 Device

Harmony LED-1 Surgical Lighting System (K072072)

3. Device Description

The Harmony vLED Surgical Lighting System 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 Harmony vLED Surgical Lighting System is designed to replace existing surgical lights, or to be installed as part of major renovations to existing facilities or in new facilities.

The Harmony vLED Surgical Lighting System accessories are as follows:

- STERIS ACT Interface
- Camera Module
- Dual or Single Flat Panel Monitors
- 24VDC Battery Backup support
- Remote Power Module Unit
- Sterile Disposable Handle Covers

4. Intended Use

The proposed Harmony vLED Surgical Lighting System 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 vLED 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 vLED Surgical Lighting System, like its predicate device, is a variable pattern, variable intensity surgical light designed to provide visible illumination of the surgical field and the patient and to provide optional video-visual procedural support for the hospital staff during surgical procedures. The proposed device has the same function, intended use, components, technology, and performance as the predicate device, Harmony LED-1 Surgical Lighting System (K072072) manufactured and owned by STERIS Corporation.

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

6. Performance Testing

Performance testing was conducted to verify that the Harmony vLED Surgical Lighting System meets 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
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR 17 2010

STERIS Corporation
% Mr. Robert F. Sullivan
Senior Director, Regulatory Affairs
5960 Heisley Road
Mentor, Ohio 44060

Re: K100395
Trade/Device Name: Harmony vLED Surgical Lighting System
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FST
Dated: February 12, 2010
Received: February 16, 2010

Dear Mr. Sullivan:

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): K100395

Device Name: Harmony vLED Surgical Lighting System

Indications For Use:

The Harmony vLED Surgical Lighting System 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.

Prescription Use _____ AND/OR Over-The-Counter Use ____X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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

510(k) Number K100395