K013242

DEC 1 3 2001

510(k) SUMMARY
Pertaining to the Safety and Effectiveness of the Amsco® Harmony™ Surgical Lighting and Media System

Submitter Information: STERIS Corporation
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Date Summary Prepared: September 26, 2001

Name of the device: Amsco® Harmony Surgical Lighting and Media System

Common or usual name of the device: Light, Surgical

Classification name of the device: Surgical Lamp

Predicate Devices: Amsco SQ240 Surgical Light, Hill-Rom BrightStar Surgical Light and Berchtold Chromophare D650 Surgical Lights

Device Description: The Amsco Harmony Surgical Lighting and Media System is a family of variable pattern, variable intensity surgical lights designed to provide visible illumination of the surgical field or the patient and to provide audio-visual procedural support for the O.R. staff. The Amsco Harmony Surgical Lighting and Media System consists of a center-mounted suspension, which supports horizontal arms of possible differing lengths and lighthead assemblies and operates via an electronic controller. Optional features for the system include a fiber optic light for task lighting, voice control of the system via the HERMES Operating Room Control Center, video camera integrated in surgical lighthead, optional standard or flat screen monitor or a high end audio visual system. The system components can be arrayed to produce various system configurations depending upon the needs of the user. The Amsco Harmony Surgical Lighting and Media System has a sterile disposable sheath for positioning of the light as needed and maintenance of the sterile field during surgical procedures. The sterile sheath is latex free and is made of approved medical grade material. The Amsco Harmony Surgical Lighting and Media System is designed to assure compliance with IEC 60601-2-41 (Ed.1.0 (2000-02) Medical Electrical Equipment - Part 2-41: Particular Requirements for the Safety of Surgical Luminaires and Luminaires for Diagnosis, IEC 60601-1 (Electrical Safety) and IEC 60601-1-2 (Electromagnetic Compatibility). The device carries the ETL (to UL 2601-1) and cETL (to CAN/CSA C22.2 No. 601.1-M90) markings.

Intended Use: The Amsco Harmony Surgical Lighting and Media System is a family of variable pattern, variable intensity surgical lights designed to provide visible illumination of the surgical field or the patient and to provide audio-visual procedural support for the O.R. staff. The device is intended to be used by surgeons and other medical care practitioners in a surgical setting.

Substantial Equivalence: The Amsco Harmony Surgical Lighting and Media System is substantially equivalent to the Amsco SQ240 Surgical Light, Hill-Rom BrightStar Surgical Light and Berchtold Chromophare Surgical Lights in function and intended use. Similarities and differences are listed below.

Items in **BOLD** are specifically requested in the Surgical Lamp Guidance Document

Predicate Device	Amsco Harmony	Amsco SQ240	Hill-Rom BrightStar (Prima)	Berchtold Chromophare "D" series
Illumination Area Light beam diameter	large: 6-14" medium: 5-12" small: 8"	178mm - 216mm (7-8.5")	280mm (11")	180mm - 280mm (7.1-11")
Illumination Area Light beam depth	30"	660mm (26")	510mm (20")	800mm (31.5")
Light focusing mechanism	Adjustable	Fixed	Adjustable	Fixed
Illumination @ 1m Foot-candles (Lux)	large: 13,000 (140,000) medium: 12,000 (130,000) small: 6,000 (65,000)	12,000 (130,000)	12,000 (130,000)	9,293 (100,000)
Color Temperature (°K)	4,400°K	4,400°K	4,200°K	4,500°K
UV (≤400nm) Output (watts/cm^2)	< .001 watts/cm^2	< .014 watts/cm^2	Not Available	Not Available
Light source	Tungsten Halogen Bulb	Tungsten Halogen Bulb	Halogen Quartz Bulb	Xenon Halogen Bulb
UV light filter mechanism	Dichroic Reflector (cold filter)	Dichroic Reflector (cold filter)	IR Glass	Glass/film
Adjustable pattern	Yes	Yes	Yes	Yes
Focal length	1 meter	42 inches	1 meter	1 meter
Rotation	360°	360°	360°	360°
Mounting options	single, dual, triple arm; optional "H" frame; optional AV arm; wall mount; floor stand	single, dual or triple arm; track; optional AV arm	Ceiling from center point	Ceiling from center point
Number of lamps	large: 1main, 1 reserve (auto-lamp change) medium: 1main, 1 reserve small: 1main, no reserve	1main, 1 reserve	1main, 1 reserve	1main, 1 reserve
Lamp voltage	large & medium: 21VDC small: 24 VDC	22 VDC	24 VDC	22.7 VDC

The Amsco Harmony Surgical Lighting and Media System is substantially equivalent to the predicate Surgical Lights. The minor differences described above between the Amsco Harmony Surgical Lighting and Media System configuration and that of the predicate Surgical Lights do not raise any new issues of safety or effectiveness. The intended use, basic technology, and performance characteristics of the systems are the same. The device does not contact the patient, so biocompatibility is not a concern.

Discussion of non-clinical tests

Like the predicate device(s), the Amsco Harmony Surgical Lighting and Media System will utilize existing lighting technology to position the light to deliver illumination to the operative site. Performance specifications such as, optical characteristics, drift-free performance, and surgical asepsis control through the use of disposable sterile covers are among the aspects that have been examined to compare to the predicate to help prove substantial equivalence. Dimensional specifications and/or the ergonomics of patient-user interface have been examined to ensure the device meets human factors considerations.

Discussion of clinical tests

For the Amsco Harmony Surgical Lighting and Media System clinical testing was not performed; bench testing is sufficient to prove the safety and efficacy of the device.

Conclusions drawn from the non-clinical and clinical tests

Based on the non-clinical testing of the Amsco Harmony Surgical Lighting and Media System, there are no new questions of safety or efficacy that have been raised. The Amsco Harmony Surgical Lighting and Media System meets its intended use of effectively providing visible illumination of the surgical field or the patient.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 3 2001

Laura Green
Manager, Regulatory Affairs
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060-1834

Re: K013242
Trade Name: Amsco Harmony Surgical Lighting and Media System
Regulation Number: 878.4580
Regulation Name: Surgical Lamp
Regulatory Class: II
Product Code: FTD
Dated: September 27, 2001
Received: September 28, 2001

Dear Ms. Green:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker, MP

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number (if known) K013242

Device Name Amsco ® Harmony Surgical Lighting and Media System

Indications for Use

The Amsco Harmony Surgical Lighting and Media System is a family of variable pattern, variable intensity surgical lights designed to provide visible illumination of the surgical field or the patient and to provide audio-visual procedural support for the O.R. staff.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Walker

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

510(k) Number K013242

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)