K070442

510(k) SUMMARY

POWERLED™ Surgical Light System

MAR 16 2007

Submitted by: Getinge USA, Inc. (as MAQUET S.A.'s US Agent)
1777 E Henrietta Road
Rochester, NY 14623-3133

Contact Person: Kevin M. Tompkins
Quality Analyst
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Date prepared: February 13, 2007

Proprietary Name: POWERLED™ Surgical Light System

Common Name: Surgical Light

Device Classification: Surgical Lamp (78 FSY)

Class II, as listed per 21 CFR 878.4580

Predicate Device: ALM X'TEN® (X10) Surgical Light System (K040735)

Description of Device:

The POWERLED™ Surgical Light System is a new product designation intended to identify a family of surgical lights that will use a similar set of design principles as the ALM X'TEN® (X10) Surgical Light Systems.

The POWERLED™ Surgical Light provides a broadened set of features and options that include LEDs as the main light source as well as an added optional automatic head recognition system feature as a result of this redesign effort.

The POWERLED™ Product Family currently has multiple configurations available, as shown within Table 1.

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Table 1:

Article code	Alias Code	Description
ARD568411110C	PWD70SF	POWERLED SURGICAL LIGHT, PWD70SF, CEILING MOUNTED, ONE POWERLED CUPOLA INCLUDING AMBIENT LIGHT (LEDINSIDE FUNCTION), SINGLE FORK, 1150MM SA SUSPENSION
ARD568411210C	PWD77SF	SAME AS PWD70SF, TWO POWERLED CUPOLAS
ARD568411511C	PWD70SFXS09	SAME AS PWD70SF, AND ONE FLAT SCREEN (<9KG)
ARD568411512C	PWD70SFXS21	SAME AS PWD70SF, AND ONE FLAT SCREEN (<21KG)
ARD568411513C	PWD70SFXD24	SAME AS PWD70SF, AND TWO FLAT SCREENS
ARD568413110C	PWD70SFV	SAME AS PWD70SF AND VIDEO PREWIRING
ARD568413210C	PWD77SFV	SAME AS PWD77SF AND VIDEO PREWIRING
ARD568413251C	PWD77SFVXS09	SAME AS PWD77SF, VIDEO PREWIRING AND ONE FLAT SCREEN (<9KG)
ARD568413252C	PWD77SFVXS21	SAME AS PWD77SF, VIDEO PREWIRING AND ONE FLAT SCREEN (<21KG)
ARD568413253C	PWD77SFVXD24	SAME AS PWD77SF, VIDEO PREWIRING AND TWO FLAT SCREENS
ARD568413258C	PWD77SFSC07	SAME AS PWD77SF AND ONE CAMERA SUPPORT UNIT
ARD568413511C	PWD70SFVXS09	SAME AS PWD70SF, VIDEO PREWIRING AND ONE FLAT SCREEN (<9KG)
ARD568413512C	PWD70SFVXS21	SAME AS PWD70SF, VIDEO PREWIRING AND ONE FLAT SCREEN (<21KG)
ARD568413513C	PWD70SFVXD24	SAME AS PWD70SF, VIDEO PREWIRING AND TWO FLAT SCREENS
ARD568411110C	PWD70SFR	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568411210C	PWD77SFR	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568411511C	PWD70SFR XS09	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568411512C	PWD70SFR XS21	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568411513C	PWD70SFR XD24	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568413110C	PWD70SFVR	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568413210C	PWD77SFVR	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568413251C	PWD77SFVR XS09	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568413252C	PWD77SFVR XS21	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568413253C	PWD77SFVR XD24	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568413258C	PWD77SFR SC07	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568413511C	PWD70SFVR XS09	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568413512C	PWD70SFVR XS21	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568413513C	PWD70SFVR XD24	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568421110C	PWD70DF	POWERLED SURGICAL LIGHT, PWD70DF, CEILING MOUNTED, ONE POWERLED CUPOLA INCLUDING AMBIENT LIGHT (LEDINSIDE FUNCTION), DOUBLE FORK, 850MM SA SUSPENSION

Article code	Alias Code	Description
ARD568421210C	PWD77DF	SAME AS PWD70DF, TWO POWERLED CUPOLAS
ARD568421511C	PWD70DFXS09	SAME AS PWD70DF, AND ONE FLAT SCREEN (<9KG)
ARD568421512C	PWD70DFXS21	SAME AS PWD70DF, AND ONE FLAT SCREEN (<21KG)
ARD568421513C	PWD70DFXD24	SAME AS PWD70DF, AND TWO FLAT SCREENS
ARD568423110C	PWD70DFV	SAME AS PWD70DF AND VIDEO PREWIRING
Article code	Alias Code	Text EN
ARD568423210C	PWD77DFV	SAME AS PWD77DF AND VIDEO PREWIRING
ARD568423251C	PWD77DFVXS09	SAME AS PWD77DF, VIDEO PREWIRING AND ONE FLAT SCREEN (<9KG)
ARD568423252C	PWD77DFVXS21	SAME AS PWD77DF, VIDEO PREWIRING AND ONE FLAT SCREEN (<21KG)
ARD568423253C	PWD77DFVXD24	SAME AS PWD77DF, VIDEO PREWIRING AND TWO FLAT SCREENS
ARD568423258C	PWD77DFSC07	SAME AS PWD77DF AND ONE CAMERA SUPPORT UNIT
ARD568423511C	PWD70DFVXS09	SAME AS PWD70DF, VIDEO PREWIRING AND ONE FLAT SCREEN (<9KG)
ARD568423512C	PWD70DFVXS21	SAME AS PWD70DF, VIDEO PREWIRING AND ONE FLAT SCREEN (<21KG)
ARD568423513C	PWD70DFVXD24	SAME AS PWD70DF, VIDEO PREWIRING AND TWO FLAT SCREENS
ARD568421110C	PWD70DFR	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568421210C	PWD77DFR	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568421511C	PWD70DFR XS09	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568421512C	PWD70DFR XS21	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568421513C	PWD70DFR XD24	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568423110C	PWD70DFVR	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568423210C	PWD77DFVR	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568423251C	PWD77DFVR XS09	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568423252C	PWD77DFVR XS21	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568423253C	PWD77DFVR XD24	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568423258C	PWD77DFR SC07	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568423511C	PWD70DFVR XS09	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568423512C	PWD70DFVR XS21	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM
ARD568423513C	PWD70DFVR XD24	SAME AS ABOVE WITH HEAD RECOGNITION SYSTEM

Note: additional model configurations are planned for development. These will incorporate MAQUET POWERLED™ lighthead subassemblies.

Intended Use:

The POWERLED™ Surgical Lights are intended to be used to provide visible illumination of the surgical area or the patient.

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An "LED inside" feature is available which produces lower intensity levels of ambient light, intended for minimally invasive surgery, procedures and examination.

An added optional patented automatic head recognition system feature is available to reduce the heat projected on to the surgeon's head, and to compensate for loss of illumination due to an obstacle in front of the cupola.

Non-clinical Comparisons to Predicate Device

The POWERLED™ Surgical Light (subject device) is similar to the predicate device with the following modifications:

- Modified light head design, updating its appearance and light source.
- Change of power supply.
- Modified LEDinside feature, updating its appearance using three LEDs. This ambient light, used for minimally invasive surgery applications, has five light level adjustments.
- Added optional patented automatic head recognition system feature to reduce the heat projected on to the surgeon's head, and to compensate for loss of illumination due to an obstacle in front of the cupola

Test Data:

The test data supports conformance to:

- UL 60601-1 *Standard for Medical Electrical Equipment, Part 1: General Requirements for Safety*
- CSA C22.2 No. 60601.1 *Medical Electrical Equipment, Part 1: General Requirements for Safety*
- CSA C.22.2 No. 60601-2-41 *Medical electrical equipment – Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnostics*
- IEC 60601-2-41 *Medical electrical equipment – Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnostics*
- EN 60601-1-2 *Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests*
- FCC Part 15
- Software used in the POWERLED™ Surgical Light was tested according to the appropriate FDA Software Guidance Documents, per its determination as a Minor Level of Concern.

Clinical Data:

No clinical data is required for this device classification submission.

Conclusion:

The modifications incorporated into the POWERLED™ Surgical Light System design use those desired design features from ALM X'TEN® (X10) Surgical Light Systems. Based upon the information provided herein this 510(k) Premarket Notification, we conclude that POWERLED™ Surgical Light Systems are substantially equivalent to the predicate device(s) and are safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2007

Maquet S.A.
% Getinge USA, Inc.
Mr. Kevin M. Tompkins
Quality Analyst
1777 East Henrietta Road
Rochester, New York 14623

Re: K070442
Trade/Device Name: MAQUET POWERLED™ Surgical Light System
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FSY
Dated: February 13, 2007
Received: February 15, 2007

Dear Mr. Tompkins:

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.

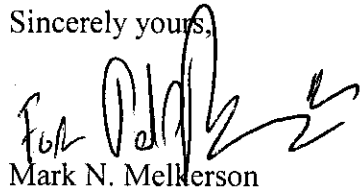
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Device Name: MAQUET POWERLED™ Surgical Light System

Indications for Use:

MAQUET POWERLED™ Surgical Light Systems are intended to be used to provide visible illumination of the surgical area or the patient.

An "LED inside" feature is available which produces lower intensity levels of ambient light, intended for minimally invasive surgery, procedures and examination.

An added optional patented automatic head recognition system feature is available to reduce the heat projected on to the surgeon's head, and to compensate for loss of illumination due to an obstacle in front of the cupola.

Mark N Mellerson

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

510(k) Number K070442

Prescription Use ✓ 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)