K113679

JAN 12 2012

510(k) Summary
As required by section 807.92

LUCEA LED® Surgical Light System

Submitter's Name & Address	MAQUET S.A.S. Parc de Limère Avenue de la Pomme de Pin CS 10008 Ardon 45074 Orléans - Cedex 2 France
Submitter of this submission	Ms. Marie-Françoise Cabel Director, Quality and Regulatory Affairs Maquet S.A.S Phone: +33 238 25 88 72 Email: marie-francoise.cabel@maquet-sa.fr
Applicant Correspondent	Ms. Whitney Törning Director, Regulatory Affairs Maquet Inc. 45 Barbour Pond Drive Wayne, NJ 07470 Phone: 973-709-7994 Fax: 973-973-807-9210 Email: whitney.torning@maquet.com
Date prepared	December, 9th 2011
Proprietary Name	LUCEA LED® Surgical Light System
Common Name	Surgical Light
Device product codes	FTD (light, surgical) for ceiling and wall-mounted models FSS (light, surgical, floor standing) for floor standing models
Device classification	Class II, acording to regulation number 21 CFR 878.4580

Predicate Device identification

- MAQUET POWERLED™ Surgical Light System – 510(k) No. K070442
- MAQUET BLUE 30 & 80 Surgical Light System (ceiling mounted) – 510(k) No. K954169
- MAQUET BLUE 80 Hospital Surgical Light System (floor standing) – 510(k) No. K970886

371

 k 113679

Device description:

MAQUET LUCEA LED® Surgical Light Systems have been developed in order to provide any operating room with LED technology. An innovative design combined with a functional shape offers an efficient product to the surgical staff.
Designed for minor surgery, LUCEA LED® Surgical Lights provide high quality illumination through LED technology without any compromises on the major enhancements offered by MAQUET surgical lights.

The LUCEA LED® Surgical Lights are well-suited for installation in surgical suites, examining rooms, doctor's surgeries and external consultations.

The LUCEA LED® product family is available in the following versions:

Device name	Device Description
WALL MOUNTED VERSIONS	
LCA 50 WALL	LUCEA LED 50 SURGICAL LIGHT, WALL MOUNTED VERSION WHICH INCLUDES A LUCEA 50 LIGHTHEAD, A WALL ERGODISC SUSPENSION AND A POWER SUPPLY KIT
LCA 100 WALL	LUCEA LED 100 SURGICAL LIGHT, WALL MOUNTED VERSION WHICH INCLUDES A LUCEA 100 LIGHTHEAD, A WALL ERGODISC SUSPENSION AND A POWER SUPPLY KIT
CEILING MOUNTED VERSIONS	
LCA DUO 50	LUCEA LED DUO 50 SURGICAL LIGHT, CEILING MOUNTED, WHICH INCLUDES TWO LUCEA 50 LIGHTHEADS - UNLIMITED ROTATION ON CENTRAL AXIS, ERGODISC SUSPENSION
LCA 50	LUCEA LED 50 SURGICAL LIGHT, CEILING MOUNTED, WHICH INCLUDES A LUCEA 50 LIGHTHEAD - UNLIMITED ROTATION ON CENTRAL AXIS, ERGODISC SUSPENSION
LCA 100 V	LUCEA LED 100 SURGICAL LIGHT, CEILING MOUNTED, WHICH INCLUDES A LUCEA 100 LIGHTHEAD - UNLIMITED ROTATION ON CENTRAL AXIS, ERGODISC SUSPENSION, VIDEO PREWIRING
LCA DUO 100 V	LUCEA LED DUO 100 SURGICAL LIGHT, CEILING MOUNTED, WHICH INCLUDES TWO LUCEA 100 LIGHTHEADS - UNLIMITED ROTATION ON CENTRAL AXIS, ERGODISC SUSPENSION, VIDEO PREWIRING
LCA DUO 100+50 V	LUCEA LED 100+50 V SURGICAL LIGHT, CEILING MOUNTED, WHICH INCLUDES A LUCEA 100 LIGHTHEAD WITH VIDEO PREWIRING AND A SATELITE LUCEA 50 - UNLIMITED ROTATION ON CENTRAL AXIS, ERGODISC SUSPENSION
MOBILE VERSIONS	
LCA 50 MOBILE	LUCEA LED 50 SURGICAL LIGHT, MOBILE VERSION WHICH INCLUDES A LUCEA 50 LIGHTHEAD, A MOBILE STAND INCLUDING THE POWER SUPPLY
LCA 50 MOBILE B	LUCEA LED 50 SURGICAL LIGHT, MOBILE VERSION WHICH INCLUDES A LUCEA 50 LIGHTHEAD, A MOBILE STAND INCLUDING THE POWER SUPPLY AND A BATTERY PACK
LCA 100 MOBILE	LUCEA LED 100 SURGICAL LIGHT, MOBILE VERSION WHICH INCLUDES A LUCEA 100 LIGHTHEAD, A MOBILE STAND INCLUDING THE POWER SUPPLY
LCA 100 MOBILE B	LUCEA LED 100 SURGICAL LIGHT, MOBILE VERSION WHICH INCLUDES A LUCEA 100 LIGHTHEAD, A MOBILE STAND INCLUDING THE POWER SUPPLY AND A BATTERY PACK

372

K113679

Intended Use:

MAQUET LUCEA LED® Surgical Light Systems are intended to be used to provide visible illumination of the surgical area or the patient during surgical operations, diagnostics and treatment.

Nonclinical Comparisons to Predicate Device

The LUCEA LED® Surgical Light (subject device) is similar to the predicate devices with the following modifications:

- Modified light head design, updating its appearance: One primary lighthead (type LUCEA 100) and one secondary lighthead (type LUCEA 50).
- Added a mechanical focusing function in LUCEA 100 lightheads: Rotating the central handle makes it possible to focus the light depending on the distance from the operating field
- Added an optional zoom camera accessory integrated in LUCEA 100 lightheads to capture intraoperative images, which may then be shared, saved or broadcast.
- Added an optional infrared remote control accessory to control intensity of LUCEA 50 and LUCEA 100 lightheads, as well as an optional zoom camera.
- Added an optional triple-axis ceiling down tube which enable combinations of LUCEA 50-100 surgical light systems with 2 other medical devices.

K113679

Test Data:

Test data support conformance to:

- UL 60601-1, 1st Edition, 2006-04-26 (Medical Electrical Equipment, Part 1: General Requirements for Safety, includes National Differences for USA)
- IEC 60601-2-41:2000, Medical electrical equipment – Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnostics
- IEC 60601-1:1988 + A1:1991 + A2:1995, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- FCC Part 15 (10) Code of Federal Regulations, Title 47 – Telecommunication, Chapter 1 – Federal Communications Commission, Part 15 – Radio frequency devices, Subpart B – Unintentional Radiators, limits and methods of measurement of radio disturbance characteristics of information technology equipment

Clinical Data:

No clinical data is required for this device classification submission.

Conclusion:

The modifications incorporated into the MAQUET LUCEA LED® Surgical Light System designs use those desired design features from MAQUET POWERLED™, BLUE 30 & 80, and BLUE 80 Hospital Surgical Light Systems. Based upon the information provided herein this 510(k) Premarket Notification, we conclude that LUCEA LED® Surgical Light Systems are substantially equivalent to the predicate devices and is safe and effective when used as intended.

37

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

MAQUET S.A.S.
% Ms. Whitney Torning
Director, Regulatory Affairs
45 Barbour Pond Drive
Wayne, New Jersey 07470

JAN 12 2012

Re: K113679
Trade/Device Name: MAQUET LUCEA LED® Surgical Light System
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: NTN, FTD, FSS
Dated: January 6, 2012
Received: January 9, 2012

Dear Ms. Torning:

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 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): K113679

Device Name: **MAQUET LUCEA LED® Surgical Light System**

Indications for Use:

MAQUET LUCEA LED® Surgical Light Systems are intended to be used to provide visible illumination of the surgical area or the patient during surgical operations, diagnostics and treatment.

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)

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

510(k) Number K113679