K130513

MAY 8 2013

510(k) Summary
As required by section 807.92

TRIOP VOLISTA® Surgical Light System

Submitter's Name & Address
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Submitter of this submission
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Applicant Correspondent
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Date prepared February 26, 2013

Proprietary Name TRIOP VOLISTA® Surgical Light System

Common Name Surgical Light

Device product codes FTD
FSY

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 LUCEA LED® Surgical Light System – 510(k) No. K113679

Device description:

MAQUET TRIOP VOLISTA® 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.

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

The TRIOP VOLISTA ® product family is composed by two different lightheads, Volista 400 and Volista 600.

The System is available on ceiling versions and may be composed by one, two or three lightheads, which can be every possible combination of VOLISTA 400 and VOLISTA 600:

	Number of Lightheads								
Volista 600	0	0	0	1	1	1	2	2	3
Volista 400	1	2	3	0	1	2	0	1	0

Accessories such as integrated cameras and screen supports can be included to the TRIOP VOLISTA® Surgical Light System.

Intended Use:

MAQUET TRIOP VOLISTA Surgical lights are intended to be used to provide visible illumination of the surgical area or the patient during surgical operations, diagnosis and treatment.

Nonclinical Comparisons to Predicate Device

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

1) a minor redesign of the lighthead,

2) change in the type of camera (optional) that can be integrated to the lighthead,

3) a new type of suspension arms and mechanical connections that allows the users to easily place either a cupola or an accessory to the arms,

4) A touch-screen interface that allows the user to switch the lights on/off, control the optical parameters of the devices and the optional cameras.

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 TRIOP VOLISTA® Surgical Light System designs use those desired design features from MAQUET POWERLED™ and MAQUET LUCEA LED® Surgical Light Systems. Based upon the information provided herein this 510(k) Premarket Notification, we conclude that TRIOP VOLISTA® Surgical Light Systems are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

May 8, 2013

Maquet SAS
% Maquet Medical Systems USA
Ms. Tosin Yedess
Regulatory Affairs Specialist II
45 Barbour Pond Drive
Wayne, New Jersey 07470

Re: K130513
Trade/Device Name: TRIOP VOLISTA® Surgical Light System
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FTD, FSY
Dated: April 10, 2013
Received: April 11, 2013

Dear Ms. Yedess:

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, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130513

Device Name: TRIOP VOLISTA® Surgical Light System

Indications for Use:

MAQUET TRIOP VOLISTA surgical lights 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___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

Joshua C. Nipper -S For

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130513