MEDICAL ILLUMINATION INTERNATIONAL

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JUN 22 2010

K100388

510 (k) SUMMARY

Submitter: Medical Illumination International Inc.
547 Library St.
San Fernando, CA 91340

Contact Person: Wayne Gerow, QA / RA Manager

Trade Name: 21st Century Centurion ExceLED and System Two LED Lighting Systems

Common Name: Surgical Light

Classification Number: 21 CFR 878.4580

Product Code: FSY

Predicate Devices:

- Berchtold Chromophare E558 and E778
  510 (k): K083066 dated October 30, 2008
  Product Code: FSY

- Maquet PowerLED 500 Surgical Light
  510(k): K070442 dated March 16, 2007
  Product Code: FSY

- Skytron Aurora LED Series Surgical Light
  510 (k): K071698 dated July 6, 2007
  Product Code: FSY

- Steris Harmony LED-1 Surgical Lighting System
  510 (k): K072072 dated October 5, 2007
  Product Code FSY

- Trumpf Kreuzer Medizin iLED Surgical Lighting System
  510 (k): K061317 dated June 22, 2006
  Product Code FSY

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Device Description:

21st Century Centurion ExceLED

The proposed 21st Century Centurion ExceLED (an AC powered device) is the first generation fixed pattern / five level intensity minor surgical LED (Light Emitting Diode) light designed to provide visible illumination of the surgical field and the patient during minor surgical and non-surgical procedures.

System Two LED

The proposed System Two LED surgical Lighting System is an AC powered device which provides a focusable field of illumination for general examination and surgery. It can consist of any combination of the 3 lights (D1, D2, D3) listed below.
All 3 models will have 5-level dimming and beam size (8"-12") adjustments.
D1 = small minor surgical light / satellite
D2 = large minor surgical light
D3 = major surgical light

Intended Use:

The 21st Century Centurion ExceLED and System Two LED lights are intended to provide visible illumination of the surgical field and the patient during surgical and non - surgical procedures.

Description of Safety:

The performance of the 21st Century Centurion ExceLED and System Two LED lights meet the general requirements for safety as defined in CEI/IEC 60601-1 and IEC 60601-2-41 for Medical Electrical Equipment.

Substantial Equivalence:

The 21st Century Centurion ExceLED and System Two LED lights are similar in function, intended use, components, technology and performance to the following predicate devices:

a. Berchtold Chromophare E558 and E778 (K083066)
b. Maquet PowerLED 500 Surgical Light (K070442)
c. Skytron Aurora LED Series Surgical Light (K071698)
d. Steris Harmony LED-1 Surgical Lighting System (K072072)
e. Trumpf Kreuzer Medizin iLED Surgical Lighting System (K061317)

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Substantial Equivalence (con't):

The differences between the proposed and predicate devices are limited to differences in design, material, and operational. These differences do not raise any new issues of safety and efficiency

Performance Testing:

Performance testing was conducted to verify that the 21st Century Centurion ExceLED and System Two LED lights meet the requirements for Medical Electrical Equipment as defined in:
CEI / IEC 60601-1
IEC 60601-2-41

Wayne Gerow
QA / RA Manager
Medical Illumination International, Inc.

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

Medical Illumination International, Inc.
% Mr. Wayne Gerow
QA / RA Manager
547 Liberty Street
San Fernando, California 91340

JUN 22 2010

Re: K100388
Trade/Device Name: System Two LED
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FST
Dated: May 17, 2010
Received: May 18, 2010

Dear Mr. Gerow:

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,

David Krone

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number: K100388

Device Name: System Two LED

Indications for Use:
The System Two LED surgical Lighting System is an AC powered device which provides a focusable filed of illumination for general examination and surgery.
It can consist of any combination of the 3 lights (D1, D2, D3) listed below.
All 3 models will have 5-level dimming and beam size (8"-12") adjustments.
D1 = small minor surgical light / satellite
D2 = large minor surgical light
D3 = major surgical light

Prescription Use (Per 21 CFR 801.109 X) OR Over- the- Counter Use_____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm

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

510(k) Number K100388

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