510(k) Summary

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DEC 0 5 2013

Device Trade Names: Scintillant Surgical Lights (Dual Bent Tip Surgical Light, Scintillant Dual Straight Tip Surgical Light)

Device Common Name: Surgical Light

Device Classification: FTD, 21 CFR Part 878.4580, Surgical Lamp.

Class: II

Identification of Legally Marketed Devices: The fundamental scientific technology, design features and indications for use for the subject lights are identical to the predicate Scintillant Surgical Light K071180 (SE 06/20/07)

Device Description: The Scintillant Dual Tip Light is a sterile, single-use device designed to provide surgeons with localized brilliant white illumination of the surgical site. Utilizing an internal battery, the device is designed to stay operational for up to three hours of continuous use. Dual light tips in combination with flexible leads containing memory wire allows for the surgeon to direct light from multiple locations optimizing the illumination provided by the device and allowing for increased visibility within the surgical site.

Device Intended Use: The Scintillant Surgical Lights are intended to provide localized illumination of surgical sites.

Technological Characteristics: The technological characteristics between the predicate and proposed devices are similar. Both the predicate and proposed devices are sterile, hand-held, battery powered, surgical field illuminating devices and regarding the lighting function have the same overall intended use and indications for use. The proposed devices have a lower operating temperature than the predicate device which does not impact patient safety risk.

Discussion of

Non-Clinical Testing: Engineering Rationales were developed comparing the subject devices to the predicate surgical light. The Engineering Rationales theorized the reduction of the light source temperature posed no new risk to the patient and provided sufficient light for physicians performing surgical procedures for up to three hours. Confirmatory testing was performed and validated the Engineering Rationales.

Conclusions: There are no significant differences to functionality or intended use of the proposed devices to the Scintillant Surgical Light. The proposed device operates at a lower temperature than the predicate Scintillant Surgical Light and thus does not pose any additional risk to patient safety. Therefore, the proposed device does not raise any new questions regarding safety and effectiveness.

Given the similarities in design, materials used, power source and the identical indications, EMS concludes the Scintillant Dual Bent Tip Surgical Light and the Scintillant Dual Straight Tip Surgical Light are substantially equivalent to the predicate Scintillant Surgical Lamp cleared by the FDA in K071180 (SE 06/20/07).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Engineered Medical Solutions Co., LLC
Mr. Ryan Savage
Project Manager
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December 5, 2013

Re: K133425
Trade/Device Name: Scintillant Surgical Lights
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FDT
Dated: November 4, 2013
Received: November 14, 2013

Dear Mr. Savage:

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 contact 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. 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,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K133425

Device Name: Scintillant Surgical Lights

Indications for Use: The Scintillant Surgical Lights are intended to provide localized illumination of surgical sites.

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)

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Long H. Chen -A

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DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300369056
Date: 2013.12.05 15:18:03 -05'00'

for BSA

(Division Sign-off)
Division of Surgical Devices
510(k) Number: K133425