JUN 3 0 2014

Summary

Submitter's Information

Company: Umbel Corporation
2339 Canyon Park Dr, Diamond Bar, CA91765
Contact: Hayden Wood
Phone: (714) 784 - 5204
Email: umhayden@aol.com

Device Identification

Common Name: Surgical Light, Surgical Lamp
Propriety Name: Surgical Light
Model Name: ZF 720
Device Class: Class II
Product Code: FSY

Predicate Device Information

Predicate Device1: Stryker Visum Surgical Lighting System
510(k) number: K031068
Predicate Device2: MAQUET POWERLED Surgical Light System
510(k) number: K070442

Device Description

The Surgical Light ZF 720 is applicable for Open surgery, Endoscope surgery or other surgical procedures. With ceiling, wall and floor versions, the Surgical Light ZF 720 Systems are well-suited for various operating rooms.

The device can be adjusted the color temperature, light intensity and light focus in accordance with the different visual habit by the users. And it is workable to connect to the monitor, video or other expansion devices with the requirements of the surgical environment.

Indication for Use

The Shadowless Operation Light ZF 720 is intended to be used to provide visible illumination of the surgical area or the patient with high intensity and shadow free light during surgical procedures.

Technological Characteristics

The Surgical Light ZF 720 consists of base assembly, pendent system and light head assembly integrated into one system. The Surgical Light ZF 720 provides optimum shadow resolution and ease of maneuverability. And the extension arm on the central block possesses the movement mechanism which enables the light heads swivel in all directions.

With ceiling, wall and floor versions, the Surgical Light ZF 720 is well-suited for various operating rooms. It is also available in single, dual and triple configurations in compliance with users' requirements. The software is equipped in the device. Dispense with training before using the device.

Performance Data

The Hazard Analysis of the device is in accordance with ISO 14971 Medical Application of Risk Management to Medical Devices. The performance of product has been tested and verified by users.

Performance testing was conducted to verify the Surgical Light ZF 720 meets the requirements for Medical Electrical Equipment as defined in IEC 60601-1 and IEC 60601-2-41.

Conclusion

Based upon the information provided herein this 510(k) Premarket Notification, we conclude that Surgical Light ZF 720 is substantially equivalent to the predicate devices and is safe and effective when used as intended.

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

June 30, 2014

Umbel Corporation
Mr. Hayden Wood
Project Director
2339 Canyon Park Drive
Diamond Bar, California

Re: K132551
Trade/Device Name: ZF 720
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FSY
Dated: May 27, 2014
Received: May 28, 2014

Dear Mr. Wood:

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 Industry and Consumer Education 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 Industry and Consumer Education 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 Krause -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132551

Device Name
ZF 720

Indications for Use *(Describe)*
The Shadowless Operation Light ZF 720 is intended to be used to provide visible illumination of the surgical area or the patient with high intensity and shadow free light during surgical procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."