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Communications

Section 5 - 510(k) Summary for the Visum Blade LED Surgical Light System

DEC 30 2013

PER 21 CFR 807.92

Date:	December 26, 2013
510(k) Owner/Sponsor:	Stryker Communications
Address:	1410 Lakeside Parkway, #100 Flower Mound, Texas 75028
Establishment Number:	2031963
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Contact Person:	Trey Thorsen; Senior Regulatory Compliance Analyst
Email Address:	trey.thorsen@stryker.com
Proposed Device:	**Visum Blade LED Surgical Light System (Blade)**
Device Common Name:	Surgical Light, Surgical Lamp
Product Code:	FSY
FDA Regulation Number:	21 CFR 878.4580
Device Classification:	Class II
Predicate Devices:	Burton's AIM 200 OR Major Surgical Light (K101537). Stryker's Visum LED Surgical Light System (K060802)
Device Common Name:	Surgical Light, Surgical Lamp
Product Code:	FSY
FDA Regulation Number:	21 CFR 878.4580
Device Classification:	Class II

Device Description

The Visum Blade LED Surgical Light System (Blade) is suitable for all major and minor surgical procedures in operating rooms and all other healthcare facilities where the need for illumination exists. The light intensity is variable up to 160,000 Lux. The light quality is based upon high quality LED's to provide cool light with reduced shadow resolution.

A system consists of 1 – 4 light heads supported by a pivoting suspension system that is attached to the heath care facility's super structure by a mounting plate. The system requires at least one of the following: a power supply box, ceiling cover, drop tube, central axis and spring arm. The system may include optional end effectors such as but not limited to monitor mounts. The mounting plates may be configured to accommodate a single or tandem mount suspension system.

Independent, control of each light's intensity is via the light handle. An optional electronic wall control panel may be installed in the operating room for control by non-sterile users. Blade allows for an in-light camera option that may be added to a light head. This option requires a wall control for camera operation.

Intended Use

The Visum Blade LED Surgical Light is intended to illuminate the operative site during surgical procedures with high intensity light.

Indications for Use

The Visum Blade LED Surgical Light System is indicated to be used with various mounting configurations in operating rooms, examination rooms, emergency rooms, and all other health care facilities where the need for additional illumination exists.

Technological Comparison

Like its predicates, Blade is a ceiling mounted surgical light that is available in single or tandem light head configurations. Both of the predicates and Blade provide illumination with reduced shadow resolution. All three devices have a removable, sterilizable light handle.

Blade uses an LED light source with Fresnel lenses to direct the light. Predicate devices use LED or halogen light sources with reflectors to direct the light.

Blade has two options for control of light intensity. Control is on the light head that allows the surgeon to control the light intensity from the sterile field. This is different than the predicates. Blade also allows light intensity to be controlled through a wall control, which is an optional feature.

The predicates have spot size adjustment (mechanical focus mechanism). Blade does not have this feature. The absence of this feature reduces cost, size, and complexity of the luminaire allowing Blade be marketable to a broader range of healthcare facilities.

The differences in the technological characteristics do not impact safety or effectiveness. For a complete comparison refer to Section 13 Substantial Equivalence of this premarket notification.

Performance Testing

See Section 18, Performance, Bench.

Conclusion

The submitted information in this premarket notification shows that Blade raises no new questions of safety and effectiveness and the performance can be considered equivalent to the predicate devices. This conclusion is based on the comparison of Blade to indications/intended use, design, energy used/delivered, materials, performance, safety, effectiveness, and labeling of 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 20993-0002

December 30, 2013

Stryker Communications
Mr. Trey Thorsen
Senior Regulatory Compliance Analyst
1410 Lakeside Parkway, Suite 100
Flower Mound, Texas 75028

Re: K132747
Trade/Device Name: Visum Blade LED Surgical Light System
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FSY
Dated: November 8, 2013
Received: November 12, 2013

Dear Mr. Thorsen:

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,

Binita S. Ashar -S
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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
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Enclosure

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Communications

Indications for Use

510(k) Number (if known): K132747

Device Name: Visum Blade LED Surgical Light System

Indications for Use:

The Visum Blade LED Surgical Light System (Blade) is indicated to be used with various mounting configurations in operating rooms, examination rooms, emergency rooms, and all other health care facilities where the need for additional illumination exists.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __ ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A

Digitally signed by Long H. Chen -A
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=1300368056
Date: 2014.12.30 13:58:54 -05'00'

for BSA

(Division Sign-off)
Division of Surgical Devices
510(k) Number: K132747