K053321

JAN 19 2006

510(k) Summary

510(k) Owner: Xodus Medical, Inc.
Westmoreland Business & Research Park
702 Prominence Drive
New Kensington, PA 15068
Phone: 724-337-5500
Fax: 724-337-0555
Contact: Craig Kaforey (President)

Date Prepared: 10/26/05

Device Information

Trade/Device Name: Light Guard
Common Name: Light Handle Cover
Classification Name: Light, Surgical, Accessories
Regulation Number: 21 CFR 878.4580
Product Code: FTA
Regulatory Class: II

Predicate Device

Device Name: Qualtex Light Handle Cover
Common Name: Light Handle Cover
510 (k) Number: K911369
510 (k) Owner: Deroyal Industries, Inc.
Classification Name: General & Plastic Surgery
Regulation Number: 21 CFR 878.4800
Product Code: MDM
Regulatory Class: I

510(k) Summary

Device Description

The disposable Light Guard Light Handle Cover is made from a plastic material and is a single use item used to cover the handle of a surgical light. This device fits over the handle of a surgical light to provide a sterile barrier between sterile personnel and the non-sterile light handle.

Intended Use

The disposable Light Handle Cover is a single use sterile product. Its intended use is as a cover for surgical light handles. It is to be placed over the light handle prior to the start of a surgical procedure to provide the nurse or surgeon with a sterile protective cover to enable them to move the light during the procedure without compromising the sterility of their hands. This product does not come in contact with the patient.

Technological Characteristics Comparison

Xodus Medical Inc.'s Light Guard Light Handle Cover has the same physical characteristics, material and design as the predicate device. They are both designed to slide over a surgical light handle. Both the predicate device and Xodus Medical's device are used to provide a sterile barrier between the sterile personnel and the non-sterile light handle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 2006

Mr. Craig Kaforey
President
Xodus Medical, Inc.
702 Prominence Drive
New Kensington, Pennsylvania 15068

Re: K053321
Trade/Device Name: Light Guard Light Handle and Light Handle Cover
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FTA
Dated: November 22, 2005
Received: November 30, 2005

Dear Mr. Kaforey:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara for Buch MD

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053321

Device Name: Light Guard Light Handle and Light Handle Cover

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053321