K060802

1410 Lakeside Parkway #100
Flower Mound, TX 75028
t: 972 410 7100 f: 972 410 7001
www.stryker.com

APR 7 2006

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Communications

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Classification Name:	Light, Surgical; 21CFR §878.4580; Class II
Common Name:	Surgical Light, Surgical Lamp
Proprietary Name:	Stryker Visum™ LED Surgical Lighting System

The Stryker Visum™ LED Surgical Lighting System is substantially equivalent in safety and efficacy to the currently marketed Stryker Visum™ Surgical Lighting System, currently cleared under the pre-market notification K031068, and Med-General Technologies LLC's Dual LED Lite Engine with Illumination LED Cable Coupled to a LED Lite Head (K042382) Surgical Lamp, currently cleared under K042382.

The intended use of the Stryker Visum™ LED Surgical Lighting System is to illuminate the operative site during surgical procedures with high intensity light.

Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with requirements of the Safe Medical Devices Act, 1990.

The Stryker Visum™ LED Surgical Lighting System is intended to illuminate the operative site during surgical procedures. Light functions can be controlled from within the sterile field, from a wall mounted control panel, or through the Stryker SIDNE™ device (K022393). The Stryker Visum™ LED Surgical Lighting System will be used in indications the same as other surgical lights currently offered for commercial distribution in the United States.

The Stryker Visum™ LED Surgical Lighting System is suitable for all major and minor surgical procedures throughout the hospital. The light moves via an easy to move pivoting suspension and has a completely sealed lighthead for safety and hygiene. Intensity is variable from 50,000 Lux to 160,000 Lux and each lighthead has redundant light sources that are not affected by individual source failure. The light quality is based upon a multiple reflector design combined with a heat removing conductive path to provide shadow free, cool light.

All systems are ceiling, wall, or mobile mounted lights and each provides sufficient illumination for all types of surgical procedures. The ceiling mounted lights are available in single, dual, and triple configurations and may also be combined with a separate arm to hold a viewing monitor.

The Stryker Visum™ LED Surgical Lighting System meets the requirements set forth in FDA Guidance for Surgical Lamps, as well as electrical safety standards IEC 60601-1 and IEC 60601-2-41. The sterilizable, reusable handles meet the sterility requirements of AAMI ST37 to achieve a SAL of 10^{-6}. Therefore, the Stryker Visum™ LED Surgical Lighting System is substantially equivalent in material, design and performance to the Visum Surgical Lighting System (K031068) and is substantially equivalent in light source technology to Med General's Surgical Light (K042382).

Date:_____

Louis-Pierre Marcoux, RAC
Associate RA/QA Manager
Stryker Communications

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 2006

Stryker Communications Corp.
c/o Intertek Testing Services
Mr. Daniel W. Lehtonen
Staff Engineer – Medical Devices
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K060802
Trade/Device Name: Stryker Visum™ LED Surgical Lighting System
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FSY
Dated: March 23, 2006
Received: March 24, 2006

Dear Mr. Lehtonen:

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.

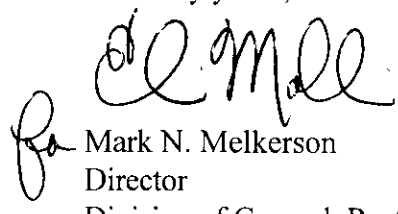
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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" (21CFR 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/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
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): K060802

Device Name: Stryker Visum™ LED Surgical Lighting System

Indications For Use:

The intended use of the Stryker Visum™ LED Surgical Lighting System is to illuminate the operative site during surgical procedures with high intensity light.

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)

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

510(k) Number K060802