K031068 1/1

AUG 1 2 2003

stryker
ENDOSCOPY

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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™ Surgical Lighting System

Predicate Device

Berchtold D650 Surgical Lighting System, currently marketed by Berchtold Corporation under the pre-market notification K922836.

Indications for Use:

The intended use of the Stryker Visum™ 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™ 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 Switchpoint device.

The Stryker Visum™ 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™ 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 75,000 Lux to 135,000 Lux and each lighthead has an automatic reserve bulb. The bulbs are easy to exchange and require no special tools.

The light quality is based upon a facetted reflector combined with a heat removing filtration device 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™ 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 sterile, disposable handles meet the sterility requirements of AAMI ST37, to and SAL of 10^{-6}. Therefore, the system is substantially equivalent in materials, design, and function to the Berchtold D650 Surgical Lighting System (K922836).

Contact:

Melissa Murphy
Regulatory Representative
Stryker Endoscopy
5900 Optical Court
San Jose, CA 95138
(408) 754-2148

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 2003

Ms. Melissa Murphy
Regulatory Representative
Stryker Endoscopy
5900 Optical Court
San Jose, California 95138

Re: K031068
Trade/Device Name: Stryker Visum™ Surgical Lighting System
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FSY
Dated: August 5, 2003
Received: August 6, 2003

Dear Ms. Murphy:

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 (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

February 17, 2003

510(k) Number if know: K031068

INDICATIONS FOR USE:

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

(Division Sign-Off)
Division of Cardiovascular
and Neurological Devices

510(k) Number K031068

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-counter Use ____

(Per 21 CFR 801.109)