5900 Optical Court
San Jose, CA 95138
t: 408 754 2000 f: 408 754 2521

DEC 19 2008

stryker®
Endoscopy

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K082813

Device Name

Proprietary Name:	Stryker LED Light Source (L9000)
Common and Usual Names:	Light Source, illuminator
Classification Name:	Light Source, Fiberoptic, Routine, CFR 21 § 876.1500

Product Description:

Intended Use: The Stryker LED Light Source is used to illuminate the site of surgery during minimally invasive surgical procedures in Arthroscopy (orthopedic surgery), Laparoscopy (general and gynecological surgery) and in Endoscopy (general, gastroenterological and ENT surgery). The light is transmitted from the source through an optical cable and a scope.

Voluntary Safety and Performance Standards: The Stryker LED Light Source will conform to the voluntary standards listed in section 5.1.

Predicate Devices: The Stryker LED Light Source is substantially equivalent in terms of safety and effectiveness to currently marketed devices including the Stryker Quantum 5000 Light Source (K961971).

Substantial Equivalence: The technological differences between the LED Light Source (L9000) and the Stryker Quantum 5000 Light Source do not raise new questions of safety or effectiveness. Therefore, the Stryker LED Light Source (L9000) is substantially equivalent to the predicate marketed device. Refer to Section 7.0 for a detailed comparison.

Contact:

23 September 2008

Desiree Crisolo
Stryker Endoscopy
5900 Optical Court
San Jose, CA 95138
Phone: 408-754-2784
Fax: 408-754-2521
Email: desiree.crisolo@stryker.com

Date:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 24 2009

Stryker Corporation
% Ms. Desiree Crisolo
Sr. Regulatory Representative
5900 Optical Court
San Jose, California 95138

Re: K082813
Trade/Device Name: Stryker LED Lightsource
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FCW
Dated: December 19, 2008
Received: November 14, 2008

Dear Ms. Crisolo:

This letter corrects our substantially equivalent letter of December 19, 2008.

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 (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.

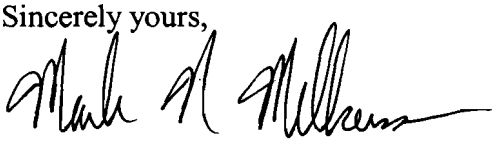
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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 (240) 276-3150 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

INTENDED USE

Device Name: Stryker LED Light Source (L9000)

510(k) Number if known: K082813

The Stryker LED Light Source is used to illuminate the site of surgery during minimally invasive surgical procedures in arthroscopy (orthopedic surgery), laparoscopy (general and gynecological surgery) and in Endoscopy (general, gastroenterological and ENT surgery). The light is transmitted from the source through an optical cable and a scope.

The light source is an integral component of a visualization system which consists of a video camera, video monitor, video recorder, video printer, light cable and scope.

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)

Neil R. Ogden for

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

510(k) Number K02813