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K053311

JAN 27 2006

stryker

Endoscopy

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Proprietary Name:	Stryker Scope Warmer
Common and Usual Name:	Endoscope Warmer, Instrument Warmer
Classification Name:	Endoscope and/or Accessories, Laparoscope, General & Plastic Surgery

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of the SMDA 1990.

The Stryker Scope Warmer is substantially equivalent in terms of safety and effectiveness to currently marketed devices, including Applied Medical's Scope Warmer (K931895).

The Stryker Scope Warmer is a new product developed by Stryker. The Stryker Scope Warmer is an endoscopic accessory, composed of PVC and sodium acetate.

The Stryker Scope Warmer is indicated for use with endoscopes. As such, this product is indicated for use prior to and during surgeries in which an endoscope is indicated. The Stryker Scope Warmer is intended to be used, prior to and during these procedures, to heat endoscopes so as to minimize fogging of the scope.

The Stryker Scope Warmer conforms to the following voluntary safety and performance standards: ISO 10993, EN 550, ASTM D999, ASTM D1140, ASTM D4332, ASTM D4728, ASTM 5276, ASTM F88-94, EN 868-1, ISO 11607 and ASTM D4169.

The technological differences between the Stryker Scope Warmer and the identified predicate device (Applied Medical's Scope Warmer (K931895) do not affect the safety or efficacy of the product, therefore, the Stryker Scope Warmer is substantially equivalent to the identified predicate devices and surgery systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2006

Ms. Crystal Ong
Regulatory Affairs Representative
Stryker Endoscopy
5900 Optical Court
San Jose, California 95138

Re: K053311
Trade/Device Name: Stryker Scope Warmer
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: November 23, 2005
Received: December 7, 2005

Dear Ms. Ong:

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 Melk 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): K053311

Device Name: Stryker Scope Warmer

Indications For Use:

The Stryker Scope Warmer is indicated for use with endoscopes. As such, this product is indicated for use prior to and during surgeries in which an endoscope is indicated. The Stryker Scope Warmer is intended to be used, prior to and during these procedures, to heat endoscopes so as to minimize fogging of the scope.

Prescription Use ✓ 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 K053311