K042454

DEC - 9 2004

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Proprietary Name:	Stryker Cassette Pump
Common and Usual Name:	Suction Irrigator
Classification Name:	Vacuum-powered Body Fluid Suction Apparatus, Irrigation Device, Gynecologic Laparoscope and Accessories, Powered Nasal Irrigator, Gastroenteroloy-urology evacuator

The Stryker Cassette Pump is substantially equivalent in terms of safety and effectiveness to currently marketed devices including the Stryker Strykeflow Suction Irrigator (K954726) and the Davol® X-Stream™ Laparoscopic Irrigation System (K003790).

The Stryker Cassette Pump is a modification of the currently marketed Stryker Strykeflow Suction Irrigator in that the batteries are rechargeable and relocated with the motor to a re-usable pump console. The single use tube set is equivalent to the Stryker Strykeflow Suction Irrigator.

The Stryker Cassette Pump is intended as a general purpose suction and/or irrigation device for use in laparoscopic and open general surgery, laparoscopic and open gynecological surgery, laparoscopic and open urologic surgery, endoscopic and open nasal surgery, open otolaryncologic surgery, and open plastic surgery. This device provides sterile irrigant solution, serves as a conduit for suction, and functions as a cannula for accessory instrumentation, including electrosurgical devices.

The Stryker Cassette Pump will conform to the following voluntary safety and performance standards including: IEC 60601-1 Medical Electrical Equipment General Requirements for Safety, IEC 60601-1-1 Collateral Standard: Medical Electrical Systems, IEC 60601-1-2 Collateral Standard: Electromagnetic Compatibility, IEC 60601-1-4 Collateral Standard: Programmable Electrical Medical, IEC 60529 Degrees of Protection Provided by Enclosure, and ISO 10993 Biological Evaluation of Medical Devices, ANSI/AAMIHF-18 2003 Electrosurgical Devices.

Laboratory and performance testing demonstrate that the characteristics of the Stryker Cassette Pump are equivalent in Safety and Effectiveness to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 9 2004

Mr. Christopher L. Cook
Regulatory Supervisor
Stryker Endoscopy
5900 Optical Court
San Jose, California 95138

Re: K042454
Trade/Device Name: Stryker Cassette Pump
Regulation Number: 21 CFR 880.6740
Regulation Name: Vacuum-powered body fluid suction apparatus
Regulatory Class: II
Product Code: GCX, HET, KQT
Dated: September 9, 2004
Received: September 10, 2004

Dear Mr. Cook:

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,

for Miriam C Provost

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

Indications for Use

510(k) Number (if known): K042454

Device Name: Stryker Cassette Pump

Indications For Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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

for emk

510(k) Number K042454