K061108

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FEB - 2 2007

stryker

Instruments

510(k) Summary

Device Sponsor:	Stryker Instruments 4100 E. Milham Avenue Kalamazoo, MI 49001 (p) 269-323-7700 (f) 269-324-5412
Registration No.:	1811755
Trade Name:	Stryker Auto Irrigation System
Common Name:	Auto Irrigator
Classification Name:	Pump, Infusion (FRN)
Equivalent to:	K030576 Anspach Irrigation Pump and Irrigation Pump II
Device Description:	The Stryker Auto Irrigation System provides on-demand irrigation using a peristaltic pump. The system consists of an enclosure containing the pump, an attachable irrigation cassette and a sensor plug.
Indications for Use:	The Stryker Auto Irrigation System is intended for use with the Maestro Pneumatic System for providing controlled, cooling irrigation during cutting, shaping and removal of bone. **Contraindications** • The Stryker Auto Irrigation System is contraindicated for use with any fluids other than those specifically for surgical irrigation.
Substantial Equivalence (SE) Rational:	The Stryker Auto Irrigation System has the same intended use as the **Anspach Irrigation Pump and Irrigation Pump II**. This device and the predicate device have the same technological characteristics, the same operating principles and have similar performance characteristics.
Safety and Effectiveness:	Based upon the comparison to the predicate devices, the Stryker Auto Irrigation System is substantially equivalent to a legally marketed device.
Submitted by:	Valerie Franck Regulatory Affairs Representative

Signature

Date submitted: 4/19/06

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 2 2007

Ms. Valerie Franck
Regulatory Affairs Representative
Stryker
Stryker Instruments Division
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K061108
Trade/Device Name: Stryker Auto Irrigation System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: January 26, 2007
Received: January 30, 2007

Dear Ms. Franck:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K061108

Device Name: Stryker Auto Irrigation System

Indications for Use

The Stryker Auto Irrigation System is intended for use with the Maestro Pneumatic System for providing controlled, cooling irrigation during cutting, shaping, and removal of bone.

Contraindications

- The Stryker Auto Irrigation System is contraindicated for use with any fluids other than those specifically for surgical irrigation.

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)

Clinton D. Mo

K061108