K072702

MAR 19 2008

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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 AntiMic Catheter Kit
Common Name:	Antimicrobial Catheter
Classification Name:	Anesthesia, Conduction Catheters (BSO)
Equivalent to:	K051401 I-Flow: On-Q SilverSoaker Catheter K061250 Vygon: MultiCath Expert K043466 Stryker Pain Pump2
Device Description:	The Stryker AntiMic catheter is intended to be used with the Stryker Pain Pump Systems. Catheters are available in the following sizes: Standard; and 2.5", 5.0", and 10" Extended Fenestration. The Standard catheter has a closed tip with three holes arranged radially along the lateral surface at the distal end of the device. The Extended Fenestration catheters have a closed tip with multiple holes arranged radially along the lateral surface at the distal end of the device. The catheter contains an antimicrobial agent that is intended to inhibit the growth of microorganisms and reduce the possibility of the catheter becoming microbially compromised.
Indications for Use:	The Stryker AntiMic Catheter is intended to provide continuous or intermittent delivery of medication (such as local anesthetics or narcotics) to or around surgical wound sites for preoperative, perioperative, and postoperative pain management. The Stryker AntiMic Catheter is contraindicated for the epidural space and in neonatal populations. The Stryker AntiMic Catheter contains an antimicrobial agent which may destroy or inhibit the growth of microorganisms on both the

inner and outer surfaces of the catheter. The antimicrobial agent is intended to reduce the possibility that the catheter may become microbially compromised. The antimicrobial agent is not intended to be used as a treatment for existing infections.

Substantial Equivalence (SE) Rational: The Stryker AntiMic Catheter has the same intended use as the I-Flow On-Q Silver Soaker Catheter and the same technology of the antimicrobial process as the Vygon MultiCath Expert Catheter. This device and the predicate devices have the same technological characteristics, use the same patient contacting materials and have similar performance characteristics.

Safety and Effectiveness: Based upon the comparison to the predicate devices, the Stryker AntiMic Catheter is substantially equivalent to legally marketed devices.

Submitted by: Julie Pryor
Regulatory Affairs Representative

Julie Pryor
Signature

Date submitted: 9/21/07

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Julie Pryor
Regulatory Affairs Representative
Stryker Instruments
4100 East Milham Avenue
Kalamazoo, Michigan 49001

MAR 19 2008

Re: K072702
Trade/Device Name: Stryker AntiMic Catheter Kit
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: II
Product Code: BSO
Dated: February 15, 2008
Received: February 19, 2008

Dear Ms. Pryor:

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/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): _____

Device Name: Stryker AntiMic Catheter Kit

Indications for Use

The Stryker AntiMic Catheter Kit is intended to provide continuous or intermittent delivery of medication (such as local anesthetics or narcotics) to or around surgical wound sites for preoperative, perioperative, and postoperative pain management. The Stryker AntiMic Catheter Kit is contraindicated for the epidural space and in neonatal populations.

The Stryker AntiMic Catheter Kit contains an anti-microbial agent which may destroy or inhibit the growth of microorganisms on both the inner and outer surfaces of the catheter. The antimicrobial agent is intended to reduce the possibility that the catheter may become microbially compromised. The antimicrobial agent is not intended to be used as a treatment for existing infections.

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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072702