MAY 1 0 2005

4100 E. Milham Avenue
Kalamazoo, MI 49001
t: 269 323 7700 f: 800 965 6505
www.stryker.com

K043466

stryker

Instruments

510(k) Summary

Trade Name: Stryker PainPump2. Stryker PainPump2 Blockaid

Common Name: Infusion Pump; Electromechanical Ambulatory Infusion Pump

Classification Name: Pump, Infusion, PCA

Equivalent to: K042405, Stryker PainPump1 and Stryker PainPump2; K040337, I-Flow Elastomeric Pump w/ Bolus

Device Description:

PainPump2

PainPump2 is an electromechanical pump designed to deliver controlled amounts of medication to the patient for pain management and/or antibiotic delivery. Medication is delivered to the treatment site using an hourly flow rate or combination of hourly flow rate and bolus PCA (Patient Controlled Analgesia) dosing option. Pain Management routes of administration may be intramuscular, subcutaneous or epidural. Antibiotic routes of administration may be intramuscular or subcutaneous.

Indications for Use:

PainPump2

The Stryker PainPump2 delivers controlled amounts of medication and narcotics directly to the intraoperative site for pain management. The pump infuses the medication at an hourly flow rate and provided the option for patient controlled bolus doses. Medications and narcotics are infused through intramuscular, subcutaneous, and epidural routes.

The Stryker PainPump2 delivers controlled amounts of medication directly to the intraoperative site for pain management and/or antibiotic administration. The pump infuses the medication at an hourly flow rate and provided the option for patient controlled bolus doses. Medications are infused through intramuscular and subcutaneous routes.

The Stryker PainPump2 is intended for controlled delivery of local anesthetics and narcotics in close proximity to nerves for postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural, or percutaneous.

The Stryker PainPump2 is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to surgical wound sites or close proximity to nerves when compared with narcotic only pain management. This results in a reduction of hospital length of stay.

Submitted by: Jennifer Mars
Regulatory Affairs Representative

_____
Signature

Date submitted:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 10 2005

Ms. Jennifer Mars
Senior Regulatory Affairs Representative
Stryker Instruments
Instruments Division
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K043466
Trade/Device Name: Stryker PainPump2
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: April 18, 2005
Received: April 19, 2005

Dear Ms. Mars:

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.

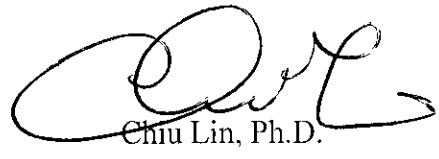
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use Statement

510(k) Number: **K043466**

Device Name: Stryker PainPump2

Indications for Use:

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Prescription Use ___X___ (Per 21 CFR 801 Subpart D) OR Over-The- Counter Use (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 Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K043466