K041738

JUL - 9 2004

Attachment 6

510 (k) Summary

Submitted by:

Karen Spranger
Baxter Healthcare Corporation
I.V. Systems Division
Route 120 and Wilson Road
Round Lake, IL 60073

Date of Submission:

June 11, 2004

Proposed Device(s):

Infusor SV
Infusor LV

Comparison Device(s):

Infusor SV
Infusor LV

Intended Use:

The intended use of the proposed devices has not changed as compared to the marketed devices. The intended use of the Infusor LV and Infusor SV Devices includes the slow, continuous intravenous, intra-arterial, subcutaneous or epidural administration of medications. It may also include the slow, continuous infusion of medications directly into an intraoperative site or subcutaneously for postoperative pain management. This is consistent with the intended use for the Infusor SV and Infusor LV devices as cleared under premarket notification K002380.

Technological Characteristics:

A modified design is being added to Baxter's Infusor line of Elastomeric Infusion Devices. Standard flow rate testing was performed to confirm performance characteristics. Routine testing in manufacturing includes 100% testing for flow rates and pressure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 9 2004

Ms. Karen Spranger
Regulatory Affairs Associate III
Baxter Healthcare Corporation
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

Re: K041738
Trade/Device Name: Infusor LV and Infusor SV
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN, MEB
Dated: June 25, 2004
Received: June 28, 2004

Dear Ms. Spranger:

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.

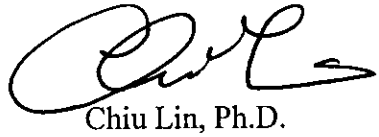
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4618. 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,



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

Attachment 3

Indications for Use

510(k) Number (if known): ~~K022380~~

Device Name: Infusor LV and Infusor SV

Indications For Use:
The modified Infusion Pumps can be utilized for slow, continuous delivery though clinically acceptable routes of administration such as intravenous (IV), intra-arterial (IA), and subcutaneous or epidural infusion of medications. In addition, the intended use of the devices includes continuous infusion of medications directly into an intraoperative site or subcutaneously for post operative pain management.

Irene Naccarato for ADW

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041738

Prescription Use ____X___ 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)