K062457

5. 510(K) SUMMARY

SEP 21 2006

DATE PREPARED:

August 8, 2006

OWNER:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

CONTACT PERSON:

Nanette Hedden
Regulatory Affairs Manager
1620 Waukegan Rd.
McGaw Park, IL 60085
Telephone: (847) 473-6281
Fax: (847) 785-5116

DEVICE NAME:

Trade name: Infusor SV Elastomeric Infusion Device

- Singleday Infusor
- Half Day Infusor
- 2 Day Infusor
- Multiday Infusor
- Seven Day Infusor

COMMON NAME:

Infusion Pump

CLASSIFICATION NAME:

Infusion Pump (21 CFR 880.5725, Product Code MEB, MEA,

PREDICATE DEVICE(S):

Table 5-1.
Previous 510(k)s

Device	Previous 510(k)	Clearance date
Single day Infusor	K802820 K905778 K982102	November 7, 1980 July 12, 1991 September 4, 1998
Half Day Infusor	K853881 K905778 K982102	December 2, 1985 July 12, 1991 September 4, 1998
2 Day Infusor	K802820 K842479 K870242 K905778 K982102	November 7, 1980 November 2, 1984 March 13, 1987 July 12, 1991 September 4, 1998
Multiday Infusor	K842905 K905778 K982102	November 1, 1985 July 12, 1991 September 4, 1998
Seven Day Infusor	K842479 K842905 K870242 K905778 K982102	November 2, 1984, November 1, 1985 March 13, 1987 July 12, 1991 September 4, 1998

DESCRIPTION OF THE DEVICE AND MODIFICATION:

Baxter's Infusor SV devices are single-use, disposable elastomeric infusion pumps designed to deliver solution at a constant preset flow rate ranging from 0.5mL/hr to 5mL/hr, depending on device configuration. The modifications made to the Infusor SV devices include replacing the glass restrictor tube and housing used in previous versions of the device with a plastic tubing flow restrictor, a coupler to connect the tubing flow restrictor to the tube set and a Luer lock connector.

STATEMENT OF INTENDED USE:

Baxter's Infusor SV Elastomeric Infusion Device is a single-use, disposable elastomeric infusion pump indicated for patients requiring slow, continuous intravenous, intra-arterial, subcutaneous or epidural administration of medications at a constant flow rate

The device is also indicated for the administration of bolus doses of medication upon patient demand when used in conjunction with the Patient Control Module. It is suitable for use in the hospital or home setting.

TECHNOLOGICAL CHARACTERISTICS:

The plastic tubing flow restrictor, Luer lock connector and coupler are replacing the current glass flow restrictor and Luer housing. These components provide the equivalent performance; however the materials differ in that the glass is replaced by plastic tubing and the coupler and Luer together replace the function of the current Luer housing by connecting the restrictor to the device tubing set and providing a Luer lock for connection to the patient's catheter.

DISCUSSION OF NONCLINICAL TESTS:

Baxter Healthcare conducts risk analyses using procedures based on ISO 14971 (2000) "Medical Devices – Application of Risk Management to Medical Devices." The risk analysis method used to assess the impact of the modification was Failure Modes and Effects Analysis (FMEA). Design verification tests based on the result of risk analysis and design input were performed to verify the modifications. Testing of the device and components included mechanical, biocompatibility, and flow rate testing. All test results meet the acceptance criteria, and prove that the modifications are appropriate.

CONCLUSION:

The Infusor SV Elastomeric Infusion Device with the modifications is as safe and effective as the predicate device and the performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2006

Ms. Nanette Hedden
Regulatory Affairs Manager
Baxter Healthcare Corporation
1620 Waukegan Road
McGaw Park, Illinois 60085

Re: K062457
Trade/Device Name: Infusor Small Volume (SV) Elastomeric Infusion Device
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: August 22, 2006
Received: August 23, 2006

Dear Ms. Hedden:

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.

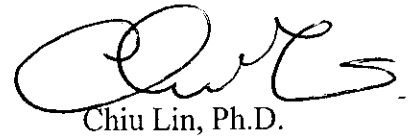
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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

INDICATIONS FOR USE

510(k) Number (if known): K062457

Device Name: Infusor Small Volume (SV) Elastomeric Infusion Devices

Indications For Use: Baxter's Infusor SV Elastomeric Infusion Device is a single-use, disposable elastomeric infusion pump indicated for patients requiring slow, continuous intravenous, intra-arterial, subcutaneous or epidural administration of medications at a constant flow rate. The device is also indicated for the administration of bolus doses of medication upon patient demand when used in conjunction with the Patient Control Module. It is suitable for use in the hospital or home setting.

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)

...on Sign-Off)
...ion of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...mber: K062457