K051253

510(k) Notification: Device Modification

JUL 15 2005

510 (K) SUMMARY

Baxter Healthcare Corporation Multirate Infusor with PCM

Preparer/Contact	Nanette Hedden Project Manager Global Regulatory Affairs 1620 Waukegan Rd. McGaw Park, IL 60085 Telephone: (847) 473-6281 Fax: (847) 785-5116 Baxter Healthcare Corporation One Baxter Parkway Deerfield, Illinois 60015
Manufacturer	Manufacturing Location: 2025695 Baxter Healthcare Corporation 17511 Armstrong Avenue Irvine, California 92614 Phone: (949) 474-6306 Fax: (949) 474-6375
Date summary was prepared:	May 6, 2005
Name(s) of the device:	Multirate Infusor (LV and SV) with PCM
Identification of predicate device(s):	Baxter Multirate Infusor (LV and SV) Baxter PCM

Description of the device and modifications:

Baxter's Multirate Infusor devices with attached PCM, are single-use disposable infusion pumps designed to deliver solution at a constant flow rate of 1-12mL/hr, depending upon the device configuration and settings, as well as allow for intermittent bolus doses of medication on patient demand.

The modifications made to the Multirate Infusor (K011317) line to incorporate a PCM (K002739) include the following:

- Inserting the same PVC "Y" connector from the single rate Infusors (K041738, K884505) before the Multirate Flow Control Module so the fluid going to the PCM can bypass the Multirate Flow Control Module. (See Section 7.4.4 for drawings showing the Multirate Infusor with PCM.)

- Providing an inline flow restrictor (the same glass flow restrictor already utilized in this line) that provides a single flow rate for filling the PCM reservoir.
- Another PVC "Y" connector is added at the output of the Multirate Flow Control Module and connects with the output of the Patient Control Module to allow for a single line to the patient which provides continuous flow as well as bolus doses when needed (the same as for the single rate Infusors with PCM attached).

All of the changes above incorporate the same technology and materials that are already incorporated in the Baxter line of elastomeric infusion devices.

Intended Use: The intended use of the Multirate Infusor with Patient Control Module includes slow, continuous, subcutaneous or epidural administration of pain medications. It may also include the slow, continuous infusion of pain medications directly into an intra-operative site, subcutaneously for postoperative pain management or the continuous infusion of a local anesthetic near a nerve for regional anesthesia. The Patient Control Module allows for intermittent bolus doses of pain medication on patient demand.

Evaluation of Design Modifications

As the basis for Baxter Healthcare's device evaluation studies and overall process for managing medical device risk, the company has performed a risk analysis 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 those modifications. All test results meet the acceptance criteria, and proved that those modifications to be appropriate.

Conclusion

The modified device, the Multirate Infusor with PCM, is substantially equivalent to the Multirate Infusor and PCM devices sold as stand alone devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2005

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

Re: K051253
Trade/Device Name: Multirate Infusor (LV and SV) with Patient Control Module
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB, MEA
Dated: June 17, 2005
Received: June 20, 2005

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 (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

510(k) Number (if known): K051253

Device Name: Multirate Infusor LV and SV with Patient Control Module

Indications For Use:
The intended use of the Multirate Infusor with Patient Control Module includes slow, continuous, subcutaneous or epidural administration of pain medications. It may also include the slow, continuous infusion of pain medications directly into an intra-operative site, subcutaneously for postoperative pain management or the continuous infusion of a local anesthetic near a nerve for regional anesthesia. The Patient Control Module allows for intermittent bolus doses of pain medication on patient demand.

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)

Richard C. Chapman for ADW

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

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