JUN 2 8 2001

K011317

SECTION 9.0

SMDA INFORMATION

SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted by:

Vicki L. Drews
Baxter Healthcare Corporation
I.V. Systems Division
Route 120 and Wilson Road
Round Lake, IL 60073

Date of Submission:

April 27, 2001

Proposed Device(s):

Multirate Infusor SV
Multirate 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 stand alone Multirate Infusor 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. The intended use of the Multirate Infusor when packaged in the kit configuration (Baxter Pain Mate Pain Management System) will be limited to use for slow, continuous infusion of medications directly into an intraoperative site or subcutaneously for postoperative pain management 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. This device can be set to flow at any one of three nominal Flow Rates indicated on the Multirate Control Module, or to the "off" position.

Standard flow rate testing was performed to confirm performance characteristics. Routine testing in manufacturing includes 100% testing for flow rates and pressure.

The Multirate Infusors will be marketed as stand alone devices as are Baxter's current Elastomeric Infusion Devices. Additionally, the Multirate Infusors may be packaged in the Baxter Pain Mate Pain Management System, a convenience kit provided for use in postoperative pain management.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 8 2001

Ms. Vicki L. Drews
Baxter Healthcare Corporation
I.V. Systems Division
Route 120 and Wilson Road
Round Lake, Illinois 60073-0490

Re: K011317
Trade/Device Name: Multirate Infusor SV; Multirate Infusor LV; Baxter Pain Management Systems
Regulation Number: 880.5725
Regulatory Class: II
Product Code: MEB
Dated: April 27, 2001
Received: April 30, 2001

Dear Ms. Drews:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 11.0

INTENDED USE

The intended use of the Multirate Infusor 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. When packaged in the kit configuration (Baxter Pain Mate Pain Management System), the intended use will be limited to the slow, continuous infusion of medications directly into an intraoperative site or subcutaneously for postoperative pain management.

Patricia Cucerite

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011317