SEP 4 1998

K 982102

## *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:***

June 12, 1998

***Proposed Device(s):***

Singleday Infusor
Infusor SV
2 Day Infusor

Multiday Infusor
Seven Day Infusor

***Comparison Device(s):***

Singleday Infusor
Infusor SV
2 Day Infusor

Multiday Infusor
Seven Day Infusor

***Intended Use:***

The modified devices have the same intended use as the comparison devices. They are indicated for slow, continuous intravenous, intra-arterial, subcutaneous or epidural administration of medications. They are also indicated for the administration of bolus doses of medication upon patient demand when used in conjunction with the Patient Control Module. These devices are suitable for use in the hospital and home setting.

***Technological Characteristics:***

A design modification is being made to Baxter's Infusor SV line of Elastomeric Infusion Devices. This modification is being made to facilitate filling and priming the device. The modification involves the relocation of the fill port to the end of the housing and the addition of a piece of coiled tubing to connect the relocated fill port to the volume indicator. Standard flow rate testing was performed to confirm performance characteristics.

JUN 12 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 4 1998

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

Re: K982102
Trade Name: Baxter Infusor SV-Elastomeric Infusion Device
Regulatory Class: Unclassified
Product Code: MEB
Dated: June 12, 1998
Received: June 15, 1998

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,

S. Sutton for

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*

## *INDICATION 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.

Patricia Cicenia
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K982102

Prescription Use ✓
(Per 21 CFR 801.109)

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