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K993387

510(K) SUMMARY

Submitted by:

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

Proposed Device:
Ipump™ Pain Management System

Predicate Device:
APII Infusion Pump, K926385, cleared 4/18/1994

Device Description and Statement of Intended Use:

The Ipump™ Pain Management System is an electronic infusion pump indicated for the controlled rate delivery of small volume parenteral fluids as prescribed by a physician. Delivery may be continuous or intermittent and may be epidural, intravenous or subcutaneous.

The Ipump™ operates using a linear peristaltic pumping mechanism and a DC motor. The power source can be either a 9 Volt battery or an AC adapter. The Ipump™ provides continuous, Patient Controlled Analgesia (PCA), and combined modes of operation. The pumps have configurable input parameters, which allow institutions to pre-select which modes of operation will be available to users and which units of measure will be used for data entry.

The principal modifications described in this submission are: (1) the addition of upstream occlusion and air detection; (2) a modified downstream occlusion mechanism; (3) a modified AC Adapter; (4) addition of a configuration download feature; (5) increased the configurable continuous infusion rate and the configurable bolus volume; (6) expanded alerts and alarms; (7) enhanced security features; (8) additional timed infusion limit and dose/hour limit configuration options; (9) an automatic restart after bolus option; (10) foreign language and international date and time format options; (11) flexible audible alert call back time; (12) option to configure the "Start" key to function as a PCA

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button; (13) enhanced pump history; (14) option for use of previous prescription the current prescription; (15) updated labeling.

The pump system includes a custom tubing set and a flexible non-vented reservoir (bag) of up to 500 mL in addition to the pump. The disposable accessories are unchanged from the predicate device.

Summary of Technological Characteristics of New Device to Predicate Devices

The technological features of the Ipump™ Pain Management System do not differ significantly from the APII Infusion Pump. The devices have similar materials, product design, and energy source and have the same intended use.

Discussion of Non Clinical Tests; Conclusions Drawn from Nonclinical Tests

Accuracy data was generated in accordance with the testing methodology defined by the IEC 601-2-24 standard. The results of testing conducted to verify the design modifications demonstrate acceptable performance of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Vicki L. Drews
Manager, Regulatory Affairs
Baxter Healthcare Corporation
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

Re: K993387
Trade Name: APII Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: October 7, 1999
Received: October 8, 1999

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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" (21 CFR 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/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

INDICATIONS FOR USE STATEMENT

Device Trade Name: Ipump™ Pain Management System

Indications for Use: The Ipump™ Pain Management System is indicated for the controlled rate delivery of small volume parenteral fluids as prescribed by a physician. Delivery may be continuous or intermittent and may be epidural, intravenous or subcutaneous.

Patricia Cucenti

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993387

Prescription Use ✓
(Per 21 CFR 801.109)

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