K040985

NOV 3 0 2004

510(k) Summary of Safety and Effectiveness

Submitted by:

Jennifer M. Paine
Manager, Global Regulatory Affairs
Baxter Healthcare Corporation
Medication Delivery
Rte. 120 and Wilson Road
Round Lake, IL 60073

Name/Classification of Device:

Infusion Pump/ Class II, 80FRN/80MEA – 21 CFR 880.5725

Trade Name:

Pump Connectivity Interface

Predicate Devices:

Alaris Medley System with MMS
B. Braun Horizon Outlook with DoseCom

Statement of Intended Use:

The Pump Connectivity Interface is a computerized wireless patient information and medication management tool that is integrated into an existing hospital network infrastructure and allows communications with external devices, including personal computers (PCs), Personal Digital Assistants (PDAs), hospital monitoring systems and Hospital Information Management Systems (HIMS). Communication of data includes infusion parameters, system configuration, history, events, trending, alarms and status. It is intended for use in professional healthcare environments that use electronic, external infusion devices.

The Pump Connectivity Interface is intended to provide trained healthcare practitioners access to additional information needed to more safely manage infusion therapy via infusion pumps. It enables remote viewing of pump status within the hospital and enables comparisons of pharmacy-entered prescription information to programmed pump settings. All data entry and validation of infusion parameters is performed by the trained healthcare professional according to a physician's order.

The Pump Connectivity Interface also enables secondary notification of pump alerts and alarms to remote users via a personal digital assistant (PDA) or similar device.

The Pump Connectivity Interface is intended for use by trained healthcare practitioners in accordance with the instructions provided in Pump Connectivity Interface labeling.

Device Description:

The Pump Connectivity Interface has been developed to expand upon previously cleared external monitoring features of legally marketed infusion pumps. As described above, the Pump Connectivity Interface is a system of hardware and software that enables external infusion pumps to be integrated into existing hospital network infrastructure. It is intended

to provide trained healthcare practitioners with access to additional information needed to more safely manage infusion therapy via external infusion pumps.

Summary of Technological Characteristics of New Device to Predicate Devices:

A comparison of the technological characteristics of the Pump Connectivity Interface to the predicate devices has been performed. The results of this comparison demonstrate that the Pump Connectivity Interface is equivalent to the marketed predicate device in technological characteristics.

Performance Data:

The performance data indicate that the device will meet specified requirements and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Robert L. Wilkinson, RAC
Director, Regulatory Affairs
Baxter Healthcare Corporation
1620 Waukegan Road
McGaw Park, Illinois 60085

Re: K040985
Trade/Device Name: Pump Connectivity Interface
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: November 23, 2004
Received: November 24, 2004

Dear Mr. Wilkinson:

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.

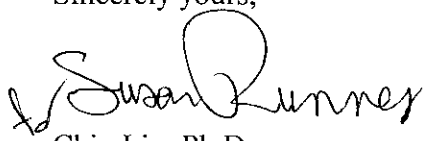
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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/dsma/dsmamain.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

Indications for Use

510(k) Number (if known): K040985

Device Name: Pump Connectivity Interface

Indications For Use:

The Pump Connectivity Interface is a computerized wireless patient information and medication management tool that is integrated into an existing hospital network infrastructure and allows communications with external devices, including personal computers (PCs), Personal Digital Assistants (PDAs) or similar display/computing devices, hospital monitoring systems, and Hospital Information Management Systems (HIMS). Communication of data includes infusion parameters, system configuration, history, events, trending, alarms and status. It is intended for use in professional healthcare environments that use electronic, external infusion devices.

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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)

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

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