JUN 3 0 2004

K041550

4 510(k) SUMMARY

1. **Submitted by:**	Abbott Laboratories, Inc. D-389. Bldg. J-45 200 Abbott Park Rd Abbott Park, IL 60064	Phone: (847) 938-3718 Fax: (847) 938-7867 Contact: Patricia Melerski
2. **Date Prepared:**	April 16, 2004	
3. **Name/Classification of Device:**	Infusion Pump, Class II 80 FRN – 21 CFR Parts 880.5725 Administration Sets 80 FPA – 21 CFR Reference: 880.5440	
4. **Trade Name of Proposed Device:**	Abbott Phoenix Infusion System with Abbott MedNet™ Software	
5. **Predicate Devices:**	Abbott Plum A+® Infusion Pump with HPL/RS with the plug-and-play Module (K031185) Abbott Gemstar™ I.V. Infusion Pump system (K023062)	

6. Proposed Device Description:

The Abbott Phoenix Infusion System with Abbott MedNet™ Software is comprised of an Abbott Phoenix Infuser and accessories. The accessories consist of dedicated infusion administration sets, an optional wireless communications module and optional software that can manage default settings, drug limit alerts and history logs through the communications connections.

The infuser is an electromechanical infusion pump (hereinafter referred to as a pump) that uses a DC motor along with an in-line cassette to meter intravenous (I.V.) fluids through a dedicated administration set. The pump is manufactured for Abbott Laboratories and distributed by Abbott Laboratories. The administration sets are manufactured by and distributed by Abbott Laboratories.

The pump is manufactured as a one-channel or two-channel fluid delivery device. The clinician can configure the pumps by connecting them together. The two-channel pump can be connected to a one-channel pump to form a three-channel pump. Two two-channel pumps can be connected together to form a four-channel pump. However, two one-channel pumps cannot be connected together, nor can more than two pumps be connected together. When the devices are connected, local communication between the pumps is accomplished through Infrared Data Association® (IrDA) sensors.

The pump's large LCD-touch screen allows the healthcare practitioner to program fluid delivery in a variety of weight- and surface area-based units such as micrograms/kg/hour, grams/m^2/hr, and other delivery specifications.

The display provides visible indication of several functions including active pump operations, alarm and program status, and fluid flow parameters.

Both the predicate and the proposed devices can be used for primary and secondary fluid delivery.

The pumps can transmit and receive data by using a cable connected to a data port directly or through a wireless communications module. Data handling is accomplished using the Abbott MedNet Software. Data can include downloading customized drug library and/or customized pump configuration, uploading event/alarm logs, triggering a nurse callback, and/or sending current pumping parameters to another computer or device. The wireless communications module allows the pump to be connected to a hospital information system or infusion medication management software system.

The pumps manufactured without a wireless board are enabled for wireless upgrade. The pumps can be converted to have wireless functionality at a later date by inserting an optional wireless communications module in the pump.

7. Statement of Intended Use:

The Abbott Phoenix Infusion System with Abbott MedNet Software is intended for the delivery of fluids, solutions, drugs, agents, nutritionals, electrolytes, blood and blood products via parenteral, enteral, intravenous, intra-arterial, subcutaneous, epidural or irrigation routes of administration.

It is intended primarily for use in the hospital setting and can be used in other acute and non-acute care areas, such as but not limited to Home Care, Nursing Homes, Mobile Intensive Care, Ambulatory Infusion Centers, Hospice, Subacute facilities, Outpatient/Surgical Centers, Long Term Care, Urgent Care, Transport and Physician Offices.

8. Summary of Technological Characteristics of New Device Compared to Predicate Device

The proposed Abbott Phoenix Infusion System with Abbott MedNet Software and the predicate devices are similar in fundamental technology (fluid delivery), programming options, materials of construction, intended use and labeling. Therefore, the Abbott Phoenix Infusion System with Abbott MedNet Software is substantially equivalent to Abbott Plum A+® Infusion Pump with HPL/RS with the plug-and-play Module and the Abbott Gemstar® I.V. Infusion Pump. The proposed device does not raise new issues of safety and effectiveness.

The substantial equivalence claim is supported by the information provided in the 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2004

Abbott Laboratories
C/O Mr. Ned Devine
Responsible Third Party Official
Entela, Incorporated
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K041550
Trade/Device Name: Hospira Phoenix Infusion System with Hospira MedNet Software
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: June 22, 2004
Received: June 24, 2004

Dear Mr. Devine:

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 (301) 594-4618. 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

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Hospira Phoenix Infusion System with Hospira MedNet Software

Indications For Use:

The Hospira Phoenix Infusion System with Hospira MedNet Software has the following indications for use:

The Hospira Phoenix Infusion System with Hospira MedNet Software is intended for the delivery of fluids, solutions, drugs, agents, nutritionals, electrolytes, blood and blood products via parenteral, enteral, intravenous, intra-arterial, subcutaneous, epidural or irrigation routes of administration.

It is intended primarily for use in the hospital setting and can be used in other acute and non-acute care areas, such as, but not limited to Home Care, Nursing Homes, Mobile Intensive Care, Ambulatory Infusion Centers, Hospice, Subacute facilities, Outpatient/Surgical Centers, Long Term Care, Urgent Care, Transport and Physician Offices.

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

510(k) Number: K941559