K042609

OCT 6 - 2004

4 510(k) SUMMARY

1. Submitted by:	Hospira, Inc. Phone:(224) 212-4897 D-040B Bldg. H2 Fax: (224) 212-5401 275 N. Field Drive Lake Forest, IL 60045 Contact: Ray Silkaitis, RPh Ph.D.
2. Name/Classification of Device:	Infusion Pump Accessory; Class II; 80 FRN 21 CFR Parts 880.5725
3. Trade Name of Proposed Device:	Hospira MedNet™ Medication Management Suite
5. **Predicate Devices**	K 042081 Plum A+®/A+®3 Infusion Systems with Hospira MedNet™ Software K030459 Medley™ with Medication Management System (Medley™ System MMS) K011975 Horizon Outlook™ with DoseCom™

5. Proposed Device Description:

The Hospira MedNet™ Medication Management Suite is an optional software product intended for use in healthcare facilities by trained healthcare professionals to facilitate networked communications (wired or wireless) between MMS compatible hospital information systems and Hospira infusion pumps, such as the Plum A+®/Plum A+®3. The feature of pre-populating infusion parameters is being added to reduce the number of manual steps to program an external infusion pump.

The MMS provides healthcare professionals with the capability to send, receive, and store information from infusion pumps. The bi-directional communication includes infusion parameters, pump default configurations, pump location, history, events, trending, alarms and status. The MMS cannot remotely start, modify, or terminate ongoing infusions.

6. Statement of Intended Use:

The Hospira MedNet™ Medication Management Suite (MMS) is intended to facilitate networked communication between MMS compatible computer systems and Hospira infusion pumps. The MMS provides trained healthcare professionals with the capability to send, receive, report, and store information from interfaced external systems, and to configure and edit infusion programming parameters.

The MMS is intended to provide a way to automate the programming of infusion parameters, thereby decreasing the amount of manual steps necessary to enter infusion data. All data entry and validation of infusion parameters is performed by a trained healthcare professional according to physician's orders.

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

The subject and predicate devices were compared and are similar in design, components and intended use. The proposed modifications do not raise new issues of safety and/or effectiveness. Therefore, the software is substantially equivalent to the predicate devices.

The claim for substantial equivalence 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

OCT 6 - 2004

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

Re: K042609
Trade/Device Name: Hospira MedNet™ Medication Management Suite
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: September 22, 2004
Received: September 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 (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

Enclosure

K042609

Indications for Use

510(k) Number (if known)

Device Name: **Hospira MedNet™ Medication Management Suite**

Indications for Use:

The Hospira MedNet™ Medication Management Suite (MMS) is intended to facilitate networked communication between MMS compatible computer systems and Hospira infusion pumps. The MMS provides trained healthcare professionals with the capability to send, receive, report, and store information from interfaced external systems, and to configure and edit infusion programming parameters.

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

510(k) Number: K042609

Prescription Use __X__ **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) (Part 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)