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AUG 2 4 2005

510(K) Summary

1. Name of Submitter: Hospira, Inc.
275 North Field Drive
Lake Forest, Illinois 60045

Owner/Operator # 9063339

2. Manufacturer and Establishment Registration Number:

Hospira, Inc. – Morgan Hill
755 Jarvis Drive
Morgan Hill, CA 95037

Establishment Registration # 2921482

3. Proprietary or Trade Name of Proposed Devices:

Hospira Plum A+® Infusion Pump System, v11.5

Hospira Plum A+®3 Infusion Pump System, v11.5

4. Common Name: Infusion Pump with IV Administration Sets

5. Device Classification, Pancode and ProCode: Class II, FRN (Infuser)
Class II, FPA (IV Administration Sets)

6. Performance Standards: No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for intravenous infusion pumps. Infusion pumps are listed in 21 CFR 880.5725.

7. Intended Use:
Intended for use in parenteral, enteral, and epidural therapies and the administration of whole blood and blood products.

8. Indications for Use:
Indicated for use in parenteral, enteral and epidural therapies and the administration of whole blood and blood products.

9. Proposed Device Description:
The Hospira Plum A+® and Hospira Plum A+®3 Infusion Pump Systems are a family of single channel and triple channel software controlled, electromechanical infusion pumps that operate on a volumetric, piston-driven, fluid displacement principle. The infusers use a stepper motor in conjunction with an in-line cassette to meter and deliver IV fluids through sterile intravenous administration sets designed to be used exclusively with both the Plum A+® and Plum A+®3. The infusers can be pole mounted.

As of May 03, 2004, both the infusers and the dedicated PlumSet® Administration Sets are manufactured and distributed by Hospira Incorporated, formerly the Hospital Products Division of Abbott Laboratories.

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10. Predicate Device Information:

Devices cleared for commercial distribution and determined to be appropriate for use as predicates are summarized in the following table.

Submission History		
510(k) #	**Title**	**Decision Date**
K042081	Plum A+ Infusion System with Hospira MedNet™ Software (v. 13.x)	08/24/2004
K024084	Abbott Plum A+ Infusion Pump, Model 12391	12/31/2002
K021350	Abbott Plum A+3 Multichannel Infusion Pump	05/14/2002
K011442	Plum A+ Infusion Pump	06/05/2001

11. Comparison to Legally Marketed Device(s)

Factors	**Subject Device(s)** Hospira Plum A+® Infusion Pump System, v11.5 Hospira Plum A+®3 Infusion Pump System, v11.5	**Primary Predicate Device(s)** Hospira Plum A+® / Plum A+®3 Infusion Pump Systems V10.3 , v11.3, v13.x
Intended Use	Intended for use in parenteral, enteral, and epidural therapies and the administration of whole blood and blood products.	Same
Indications	Indicated for use in parenteral, enteral, and epidural therapies and the administration of whole blood and blood products.	Same
Operating Principle	Volumetric, piston driven, fluid displacement principle. Stepper motor in conjunction with an in-line cassette to meter IV fluids through a dedicated intravenous administration set.	Same
Administration Sets and Fluid Contact Materials	Sterile, dedicated, non-pyrogenic, PlumSet® Administration Sets.	Same
Physical Features	Materials, Size, Weight, Input Lines, Output Lines, Power Sources, Battery Type, Power Cord	Same
Environmental Features	Operating Temperature, Storage Temperature, Relative Humidity, Pressure	Same

Factors	Subject Device(s) Hospira Plum A+® Infusion Pump System, v11.5 Hospira Plum A+®3 Infusion Pump System, v11.5	Primary Predicate Device(s) Hospira Plum A+® / Plum A+®3 Infusion Pump Systems V10.3 , v11.3, v13.x
Performance Features	Delivery Rates, VTBI Range, Dose Units, Delivery Accuracy, Delivery Modes, Therapies, Distal Occlusion Limits, Proximal Occlusion Limits, Alarm Types and Conditions, Default Drug Library.	Similiar (Improved Battery Charge Monitoring Algorithm in v11.5 and v13.x only)
BioMed Settings	Configuration settings available for customization.	Similar (Supporting software code for optional barcode wand capability removed in v11.5, disabled in v13.x)

12. Statement of Substantial Equivalence:

Compatible Hospira Plum A+® and Hospira Plum A+®3 Infusion Systems when upgraded with v11.5 software are substantially equivalent to the current predicate devices identified in the submission.

Similarities:

1) Same intended use and indications for use.
2) Same fundamental scientific technology.
3) Same physical, operational, and performance specifications.
4) Same materials of construction for all infuser components and administration sets.

13. Statement of Safety and Effectiveness

Compatible Hospira Plum A+® and Hospira Plum A+®3 Infusion Systems, when upgraded to v11.5, meet the functional claims and intended use as described in the product labeling, and are as safe and effective in terms of substantial equivalence as the predicate devices described in this submission.

Prepared and submitted by:
Patricia Melerski
Manager, Global Device Regulatory Affairs
Hospira, Inc.
275 North Field Drive
Lake Forest, IL 60045
Phone: 224/212-4880
Fax: 224/212-5401

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 4 2005

Ms. Patricia Melerski
Manager, Global Device Regulatory Affairs
Hospira, Incorporated
275 North Field Drive
Building H-2, Dept.-389
Lake Forest, Illinois 60045

Re: K052052
Trade/Device Name: Hospira Plum A+® Infusion Pump System, v11.5
Hospira Plum A+®3 Infusion Pump System, v11.5
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: July 28, 2005
Received: July 29, 2005

Dear Ms. Melerski:

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.

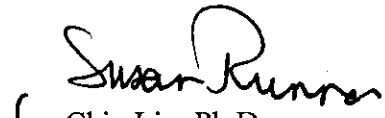
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Sincerely yours,



for 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

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Indications for Use Statement

510(k) Number (if known)

Device Name: Hospira Plum A+® Infusion Pump System, v11.5

Hospira Plum A+®3 Infusion Pump System, v11.5

Indications for Use:

Indicated for use in parenteral, enteral and epidural therapies and the administration of whole blood and blood products.

Prescription Use __X__ (Part 21 801 Subpart D) AND/OR Over-The_Counter Use_____ (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)

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

510(k) Number: K052052