AUG 2 4 2004

K042081 (P 1052)

5 510(k) SUMMARY

1. **Submitted by:**

Hospira, Inc.
D-389 Bldg. H2
275 N. Field Drive
Lake Forest, IL 60045

Phone:(224) 212-4803
Fax: (224) 212-5401

Contact: Thomas Kozma, Ph.D.

2. **Date Prepared:** June 30, 2004

3. **Name/Classification of Device:** Infusion Pump, Class II
80 FRN – 21 CFR Parts 880.5725

4. **Trade Name of Proposed Device:** Plum A+® Infusion System with Hospira MedNet™ Software
Plum A+®3 Infusion System with Hospira MedNet™ Software

5. **Predicate Devices:** Abbott Plum A+® Infusion Pump with HPL/RS Plug-and-Play Module (K031185)
Abbott Plum A+3™ Multichannel Infusion Pump (K021350)

6. **Proposed Device Description:**

The Plum A+® and A+®3 Infusion Systems with MedNet™ Software are electromechanical infusion pumps that use a stepper motor in conjunction with an in-line cassette to meter IV fluids through dedicated intravenous administration sets. The infusion pumps and administration sets are manufactured and distributed by Hospira, Inc. The Plum A+® Infusion System is a single channel pump and Plum A+®3 Infusion System is a triple channel pump.

The subject devices are modifications of the predicate infusion pumps. The modifications provide networked (Ethernet wired and wireless) communication capability through new input/output (I/O) modules as well as well as enhancement of the optional drug library software (on CD-ROMs) to include an asset management function and have resident server software capability. In addition, enhancements are being made to the user interface of the infusion pumps. These enhancements include adding additional dose units, eliminating trailing zeros after a decimal point, dynamic font sizing to allow longer drug and clinical care area (CCA) names and allowing the clinician to change the CCA as required.

In addition, the Plug 'n Play (I/O) Module is backwards compatible so that the modifications described above can be applied to existing Plum A+® pumps. The I/O

Modules and peripheral modules are backwards compatible to existing Plum A+3™ pumps and can be inserted at a factory-authorized site.

All new factory released infusion systems will be in compliance with IEC 60601-1-2 2nd Edition.

Both the predicate and the proposed devices can be used for standard, piggyback, or concurrent fluid delivery using the dedicated administration sets currently marketed under K98159. No changes to these dedicated administration sets have been made or are required in order to be used with the subject devices.

7. **Statement of Intended Use:**

The Plum A+® and Plum A+®3 Infusion System with Hospira MedNet™ Software is indicated for use in parenteral, enteral and epidural therapies and the administration of whole blood and blood products.

These are the same indications for use as the predicate devices.

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

The subject and predicate devices are similar in design, materials of construction, components, intended use, labeling and manufacturing processes. The proposed modifications do not raise new issues of safety and/or effectiveness. Therefore, these infusion systems are substantially equivalent to the predicate infusion pumps.

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

AUG 2 4 2004

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

Re: K042081
Trade/Device Name: Plum A+® Infusion System with Hospira MedNet™ Software and Plum A+®3 Infusion System with Hospira MedNet™ Software
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: August 12, 2004
Received: August 16, 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.

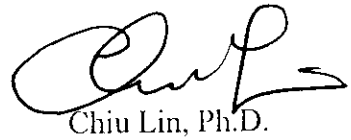
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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: **Plum A+® Infusion System with Hospira MedNet™ Software**

Plum A+®3 Infusion System with Hospira MedNet™ Software

Indications for Use:

Plum A+® and Plum A+®3 Infusion Systems with Hospira MedNet™ Software are indicated for use in parenteral, enteral and epidural therapies and the administration of whole blood and blood products.

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)

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

510(k) Number: K042081

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