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5 510(k) SUMMARY

DEC 17 2008

1. **Submitted by:**

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Lake Forest, IL 60045

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Contact: Daniela Weksler

2. **Date Prepared:** March 20, 2008

3. **Name/Classification of Device:** Infusion Pump, Class II
80 FRN – 21 CFR Parts 880.5725
Administration Sets, Class II
80 FPA – 21 CFR Parts 880.5440

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

5. **Predicate Devices:** Plum A+ Infusion System with Hospira MedNet Software (K042081)
Abbott LifeCare® Model 3 HB Pump (K890282)

6. **Proposed Device Description:**

The Plum A+® Hyperbaric Infusion System with Hospira MedNet® Software is an electromechanical infusion pump that uses a stepper motor in conjunction with an in-line cassette to meter IV fluids through dedicated intravenous administration sets in normal atmospheric Hospital settings and in Hyperbaric conditions. The infusion pump and administration sets are manufactured and distributed by Hospira, Inc. The Plum A+® Hyperbaric Infusion System is a single channel pump.

The subject device is based on modifications of the predicate infusion pumps. The modifications allow for distal pressure increases due to monoplace hyperbaric chamber pressurization and include distinct coloring to identify the pump as a hyperbaric device.

Additionally, the sets were changed so that they could be used under hyperbaric conditions. The flow regulator is colored green to identify them as hyperbaric administration sets.

In normal atmospheric conditions, both the predicate and the proposed device can be used for standard, piggyback, or concurrent fluid delivery using the dedicated administration sets currently marketed. No changes to these dedicated administration sets have been made or are required in order to be used with the

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subject devices. However, new sets have been designed for administration with monoplace hyperbaric chambers.

7. **Statement of Intended Use:**

The Plum A+® Hyperbaric 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.

Additionally, the Plum A+ Hyperbaric Infusion System with Hospira MedNet Software can be used under hyperbaric conditions in multiplace and with monoplace (Class A and B) chambers.

The indications for use of the subject devices and predicate devices are identical, with the addition of Hyperbaric Capabilities in the subject device

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, this infusion system is 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

Hospira, Incorporated
C/O Mr. Ned Devine
Responsible Third Party Official
Underwriters Laboratories Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

DEC 17 2008

Re: K081412
Trade/Device Name: Plum A+® Hyperbaric Infusion System with Hospira MedNet® Software
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: November 25, 2008
Received: December 2, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division 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) K981412

Device Name: **Plum A+® Hyperbaric Infusion System with Hospira MedNet® Software**

Indications for Use:

The Plum A+ Hyperbaric 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.

Additionally, the Plum A+ Hyperbaric Infusion System with Hospira MedNet Software can be used under hyperbaric conditions in multiplace and monoplace (Class A and B) chambers.

Prescription Use X (Part 21 CFR 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

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