510K Summary

APR 24 2007

1. **Submitted by:**

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

Contact: Nicohl R. Wilding
Phone:(224) 212-5270
Fax: (224) 212-5401

2. **Date Prepared:** February 6, 2007

3. **Name/Classification of Device:** Infusion Pump
21 CFR 880.5725, Pump, infusion
Class II,
Product code FRN

4. **Trade Name of Proposed Device:** Plum A+ ® Infusion Pump

5. **Predicate Devices:** K052052 Hospira Plum A+ Infusion Pump System v11 Cleared 08/24/2005
K024084 Abbott Plum A- Infusion Pump, Model 12391 Cleared 12/31/2002

6. **Manufacturer and Establishment Registration Number:**

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

Registration # 2921482

Sterilization Site:
N/A

7. **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.

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

The intended use is the same as for the predicate devices.

9. **Proposed Device Description:**
The proposed device is the Hospira Plum A+ Infusion Pump is a single channel software controlled, electromechanical infusion pump that operates on a volumetric, piston-driven, fluid displacement principle. The infuser uses a stepper motor in conjunction with an inline cassette to meter and deliver IV fluids through sterile

intravenous administration sets designed to be used exclusively with both the Plum A+. The infuser can be pole mounted. This pump is IEC/EN 60601-1-2:2001 compliant.

10. Summary of Substantial Equivalence

The proposed device is substantially equivalent to the predicate devices in that it has the same

- intended use,
- operating principle,
- materials of construction.

The major difference between the predicate device and the proposed device is that the subject device is compliant with IEC/EN 60601-1-2:2001.

11. Statement of Safety and Effectiveness

The subject and predicate devices are similar in design, materials of construction, components, intended use, labeling and manufacturing processes. The proposed modifications have been evaluated using bench testing in which the results met the acceptance criteria and do not raise new issues of safety and/or effectiveness.

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

APR 24 2007

Ms. Nicohl R. Wilding
Manager Global Device Regulatory Affairs
Hospira, Incorporated
275 North Field Drive H2-2
Lake Forest, Illinois 60045

Re: K070398
Trade/Device Name: Plum A+® Infusion Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: March 16, 2007
Received: April 4, 2007

Dear Ms. Wilding:

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.

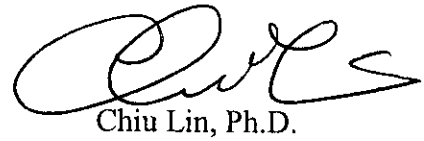
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

K070398

1 of 1

Indications for Use

510(k) Number (if known)

Device Name: Plum A+® Infusion Pump

Indications for Use:

Intended 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)

Anthony D. [illegible]

[illegible]
...ion of Anesthesiology, General Hospital,
...ion Control, Dental Devices

...(k) Number: K070398