510(K) Summary

1. Name of Submitter:

Hospira, Incorporated
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 Device: Hospira LifeCare® PCA3 Infusion System

4. Common Name: Infusion Pump

5. Device Classification, Pancode and ProCode: Class II, 80-FRN (Infusion Pump)
Class II, 80-FPA (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: The Hospira LifeCare® PCA3 Infusion System is intended for accurate, volumetric, infusion of analgesic drugs by continuous or patient-demanded (PCA) intravenous administration.

8. Indications for Use:
The LifeCare® PCA3 Infusion System is also indicated for short-term (less than 96 hours) continuous epidural administration of analgesic drugs. The epidural route can be used to provide anesthesia or analgesia. The pump must be used with sterile, dedicated, LifeCare® PCA administration sets.

9. Proposed Device Description:
The Hospira LifeCare® PCA3 Infusion System is a microprocessor controlled, pole mounted, standalone, electromechanical infusion pump that allows a patient to self administer analgesic using a patient pendant, within physician prescribed, programmed parameters. A stepper motor exerts pressure on an inserted drug vial to control the infusion of analgesic into a patient. The infuser is powered from an AC power source and has an internal battery to maintain operation for short periods when an AC power source is not available. The infuser will accept a pre-filled drug vial manufactured by Hospira, and includes one sterile empty vial that can be filled by a hospital's pharmacy.

As of May 03, 2004, both the infuser and the dedicated LifeCare® PCA administration sets are manufactured and distributed by Hospira Incorporated, formerly the Hospital Products Division of Abbott Laboratories.

10. Predicate Device Information:

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

510(k) #	Product Name	Clearance Date
K042800	LifeCare PCA® Infusion System with Hospira MedNet™ Software	10/28/2004
K022203	Abbott LifeCare® PCA3 infusion System	08/01/2002

11. Comparison to Legally Marketed Device(s)

Table 3: Summary of Comparison to Predicate Devices

Factors	Subject Device(s) Hospira LifeCare® PCA3 Infusion System	Predicate Device(s) Abbott LifeCare® PCA3 Infusion System and LifeCare PCA® Infusion System with Hospira™ MedNet Software
Intended Use	Intended for volumetric, infusion of analgesic drugs by continuous or patient-demanded (PCA) intravenous administration. It is indicated for short-term (less than 96 hours) continuous epidural administration of analgesic drugs.	Same
Indications for Use	Hospital clinical settings using sterile, dedicated, LifeCare® PCA administration sets.	Same
Operating Principle	Advancement of a syringe-like drug vial by a stepper motor driven plunger to expel drug from the vial into an attached sterile intravenous administration set designed to be used exclusively with LifeCare® PCA infusers.	Same
Administration Sets and Fluid Contact Materials	Sterile, dedicated, non-pyrogenic, latex-free LifeCare® PCA administration sets.	Same
Physical Features	Materials, Size, Weight, Power Sources, Battery Type, Power Cord	Same
Environmental Features	Operating Temperature, Storage Temperature, Relative Humidity, Pressure	Same
Performance Features	Delivery Rates, Dose Units, Delivery Accuracy, Delivery Modes, Occlusion Pressure Limits, Alarm Types and Conditions	Same
Wireless MedNet™ Software Compatibility	No wireless/network capability. Not compatible with MedNet™ Software.	Same as Abbott LifeCare® PCA3 Infusion System

12. Statement of Safety and Effectiveness

The Hospira LifeCare® PCA3 Infusion System meets the functional claims and intended use as described in the product labeling. The proposed modifications do not raise new issues of safety and/or effectiveness.

13. Statement of Substantial Equivalence:

The Hospira LifeCare® PCA3 infusion System is substantially equivalent in terms of safety and effectiveness to the predicate Abbott LifeCare® PCA3 Infusion System and the LifeCare PCA® Infusion System with Hospira MedNet™ Software based on the following characteristics.

1) Same intended use,
2) Same indication for use,
3) Same fundamental technology and operating principle,
4) Same physical, operational, environmental and performance attributes, and
5) Same materials of construction for infuser components and administration sets.

The claim for substantial equivalence is supported by the information provided in this 510(k) submission.

Prepared and submitted by:

Patricia Melerski 11/23/04

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

DEC - 6 2004

Ms. Patricia Melerski
Manager, Global Device Regulatory Affairs
Hospira, Incorporated
275 North Field Drive, Dept. 389, Bldg. H2
Lake Forest, Illinois 60045

Re: K043256
Trade/Device Name: Hospira LifeCare® PCA3 Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEA
Dated: November 23, 2004
Received: November 24, 2004

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.

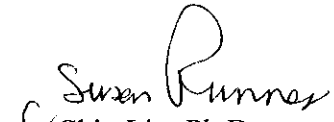
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use Statement

510(k) Number (if known) K043256

Device Name: Hospira LifeCare® PCA3 Infusion System

Indications for Use The Hospira LifeCare® PCA3 Infusion System is indicated for accurate, volumetric, infusion of analgesic drugs by continuous or patient-demanded (PCA) intravenous administration. The LifeCare PCA® Infusion System is also indicated for short-term (less than 96 hours) continuous epidural administration of analgesic drugs.

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 K043256