K042800

OCT 18 2004

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:** September 14, 2004

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

4. **Trade Name of Proposed Devices:** LifeCare PCA® Infusion System with Hospira MedNet™ Software

5. **Predicate Devices:** Abbott LifeCare® PCA 3 Infuser (K022203) and Hospira Plum A+® Infusion System with Hospira MedNet™ Software (K042081)

6. **Proposed Device Description:**

The LifeCare PCA® Infusion System with Hospira MedNet™ Software is an electromechanical infusion pump that uses a stepper motor that exerts pressure on an inserted drug vial to control the infusion of analgesic into a patient. The infuser is pole-mounted and includes an attached patient pendant that allows a patient to self-administer analgesia within physician-prescribed, programmed parameters that include delivery mode, PCA dose, lockout interval, and/or dose limits.

The LifeCare PCA® Infusion System with MedNet™ Software consists of:

- an infuser that is compliant with IEC 60601-1-2 2nd Edition requirements
- a bar code reader that recognizes Hospira- or Abbott-manufactured drug vials as well as hospital pharmacy-generated bar codes
- a Nurse Call Port
- networked communication capability (Ethernet wired and wireless) with Medication Management compatible hospital information systems
- hardware that is compatible with Hospira MedNet™ Software.

7. **Statement of Intended Use:**

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

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, the LifeCare PCA® Infusion System with Hospira™ MedNet Software 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

OCT 18 2004

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

Re: K042800
Trade/Device Name: LifeCare PCA® Infusion System with Hospira MedNet™ Software
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEA
Dated: October 8, 2004
Received: October 8, 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.

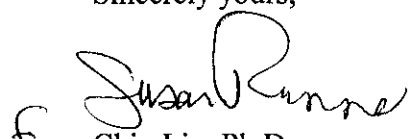
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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) K042800

Device Name: **LifeCare PCA® Infusion System with Hospira MedNet™ Software**

Indications for Use:

The LifeCare PCA® Infusion System with Hospira MedNet™ Software is indicated for accurate, volumetric, infusion of analgesic drugs by continuous or patient-demanded (PCA) intravenous administration. It is also indicated for short-term (less than 96 hours) continuous administration of analgesic drugs.

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

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