510(k) SUMMARY

Abbott LifeCare® PCA 3 Infuser

Submitted by:

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Date Prepared:

July 2, 2002

Name/Classification of Device:

PCA Infusion Pump, Class II
MEA – 21 CFR Part 880.5725
Panel 80

Proposed Device:

Abbott LifeCare® PCA 3 Infuser

Predicate Device:

Abbott LifeCare® 4100 PCA Infuser Plus II

Proposed Device Description:

The Abbott LifeCare® PCA 3 Infuser is a pole-mounted infusion pump that allows a patient to self-administer analgesia within physician programmed limits. Generally, a nurse programs the infuser with operating parameters which may include the following:

- Loading Dose
- Delivery Mode Setting, i.e., PCA, Continuous, or PCA+ Continuous
- PCA Dose
- Lockout Interval
- Rate of Continuous Flow
- 1 or 4 hour Dose Limit (factory setting at 4 hours)
- Stored Protocols (Hospital configured settings for both filled and custom vials)

Proposed Device Description: (cont'd)

The modifications in this submission consist of an update to a prior model including software revisions, an improved user interface, adding a bar code reader for drug identification and the incorporation of upgraded electrical and mechanical components that help improve fault detection.

Other changes to the proposed device include an improved liquid crystal display, a new patient pendant and the labeling has been revised to incorporate each of the modifications.

The Abbott LifeCare® PCA 3 Infuser is programmed to recognize bar coded drug vials and halts further programming if this recognition is not achieved.

The proposed device is a microprocessor-based pump that incorporates an enhanced LCD display. Pump operation is identical to prior Abbot models through the utilization of a stepper motor that exerts pressure on the drug vial so that precise amounts of analgesic drug are delivered per the prescription.

The proposed device has the same intended use as the predicate device and uses the same dedicated administration sets and the same empty and pre-filled vials as the predicate device.

Statement of Intended Use:

The Abbott LifeCare® PCA 3 Infuser is indicated for accurate, volumetric, infusion of analgesic drugs by continuous or patient demanded (PCA) intravenous administration. The Abbott LifeCare® PCA 3 Infuser is also indicated for short-term continuous (less than 96 hours) administration of analgesic drugs.

Summary of Technological Characteristics of New Device Compared to Predicate Device

The proposed pump has a similar design, the same intended use, the same method of operation and the same materials of construction as the currently marketed PCA Infuser Plus II.

Abbott proposes to modify the predicate device through enhancements to electrical and mechanical components. The major modification is the incorporation of a bar code reader that has been integrated into the enhanced software.

When the practitioner places a vial into the pump, the bar code reader electronically scans the vial for recognition of the drug and the drug concentration. If recognition is achieved then programming will proceed. If the vial is not recognized then the pump will stop and not allow any further programming.

The Abbott LifeCare® PCA 3 Infuser has been updated to include a modified user interface, a new patient pendant, an LCD display to show the dose delivered, a new user manual and new TIP cards to aid the user in programming the pump in the healthcare setting.

Visual and audible alarms are activated by deviations from established parameters. Modifications to the alarms from the predicate device are based on the addition of the bar code reader and new confirmation screens.

Lastly, the proposed device incorporates revised software that provides for a reordering of data entry steps, the inclusion of confirmation screens and improved clarity when selecting units of drug concentration.

These differences do not raise new issues of safety and effectiveness nor do they alter the fundamental technology of the Abbott LifeCare ® 4100 PCA Infuser Plus II – the predicate device.

Discussion and Conclusions from Nonclinical Tests:

Data regarding the functional performance of the proposed Abbott LifeCare® PCA 3 Infuser has been generated and reviewed.

The results of testing conducted to validate and verify the design modifications demonstrate acceptable performance of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 1 2002

Mr. Frank Pokrop
Associate Director, Regulatory Affairs
Hospital Products Division
Abbott Laboratories
200 Abbott Park Road
Department-389, Building J-45
Abbott Park, Illinois 60064-6157

Re: K022203
Trade/Device Name: Abbott LifeCare® PCA 3 Infuser, Model 12384
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEA
Dated: July 3, 2002
Received: July 5, 2002

Dear Mr. Pokrop:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
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) K022203

Device Name: Abbott LifeCare® PCA 3 Infuser

Indications For Use: The Abbott LifeCare® PCA 3 Infuser is indicated for volumetric infusion of analgesic drugs by continuous or patient demanded (PCA) intravenous administration. The Abbott LifeCare® PCA 3 Infuser is also indicated for short-term continuous (less than 96 hours) epidural administration of analgesic drugs.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use**____
(per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K022203