K02 4084

DEC 31 2002

510(k) SUMMARY

Abbott Plum A+® Infusion Pump

1. Submitted by:

Frank Pokrop
Associate Director,
Regulatory Affairs
Abbott Laboratories
D-389. Bldg. LFJ45
Abbott Park, IL 60064

2. Date Prepared:

December 10, 2002

3. Name/Classification of Device:

Infusion Pump, Class II
80 FRN – 21 CFR Parts 880.5725

4. Proposed Device:

Abbott Plum A+® Infusion Pump, List Number, 12391

5. Predicate Device:

Abbott Plum A+® Infusion Pump

6. Proposed Device Description:

The Abbott Plum A+® Infusion Pump is an electromechanical infusion pump that uses a stepper motor in conjunction with an in-line cassette to meter IV fluids through a dedicated intravenous administration set that is also manufactured and distributed by Abbott Laboratories.

The subject and predicate devices have identical indications for use. Abbott proposes to modify the predicate device through software changes, minor changes to mechanical parts and labeling changes.

The featured software changes include: providing users with a choice to select the manufacturer's recommended units of measure for drug administration, updating the drug list, adding a confirmation screen before allowing therapy to begin, including a standby function and adding a password protected keypad.

6. Proposed Device Description: (cont'd)

These proposed changes along with the updated drug list are intended to potentially aid in medication error reduction by highlighting the drug to be infused and the units of measure for drug administration as shown in the manufacturer's package insert.

The user interface of the infusion pump allows the healthcare practitioner to program fluid delivery through a variety of weight and medication based units such as micrograms/kg/hour, grams/hr and other delivery specifications.

Like the predicate device, the proposed device includes: a nurse call function, a computer data port, a drug list, and a bar code wand. The display on the pump provides visible indication of several functions including active pump operations, alarm and program status and the parameters of fluid flow for one or both incoming fluid lines.

Both the predicate and the proposed devices can be used for standard, piggyback, or concurrent fluid delivery.

7. Statement of Intended Use:

The pump is intended for use in parenteral, enteral and epidural therapies and the administration of whole blood and blood products.

This is the same intended use as the predicate device.

The pump must be used with sterile, dedicated, intravenous PlumSet® administration sets.

8. Summary of Technological Characteristics of New Device Compared to Predicate Device

Both pumps use the same software language. The proposed pump has similar design, materials of construction, components, labeling and manufacturing processes as the currently marketed Abbott Plum A+® Infusion Pump.

These differences do not raise new issues of safety and effectiveness nor do they alter the fundamental technology of the predicate device.

9. Discussion and Conclusions from Nonclinical Tests:

Data regarding the functional performance of the proposed Abbott Plum A+® Infusion Pump has been generated and reviewed.

The results of testing conducted to validate and verify the design modifications demonstrate acceptable performance of the device. There are no new issues of safety or effectiveness raised by the Plum A+® with version 11.3 software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 31 2002

Mr. Frank Pokrop
Associate Director, R/A
Abbott Laboratories
200 Abbott Park Road
Dept. 0389, Bldg. LFJ45
Abbott Park, Illinois 60064-6133

Re: K024084
Trade/Device Name: Abbott Plum A+® Infusion Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: December 10, 2002
Received: December 11, 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), 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 yours,

Joshua Hibbert-Lewis for,

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): K024084

Device Name: Abbott Plum A+® Infusion Pump

Indications For Use: Abbott Plum A+® Infusion Pump has the following indications for use:

Indicated for use in parenteral, enteral and epidural therapies and the administration of whole blood and blood products.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (per 21 CFR 801.109) OR Over-The_Counter Use_____

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K024084