MAY 1 4 2002

K021350



# 510(k) SUMMARY

**Abbott Plum A+3™ Multichannel Infusion Pump**

**Submitted by:**

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Abbott Park, IL 60064

**Date Prepared:**

April 22, 2002

**Name/Classification of Device:**

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

**Proposed Device:**

Abbott Plum A+3™ Multichannel Infusion Pump

**Predicate Device:**

Abbott Plum A+™ Single Channel Infusion Pump

**Proposed Device Description:**

The Abbott Plum A+3 infusion pump consists of three independent Plum A+ pumping units each identical to each other, housed in a single enclosure. It is an electromechanical infusion pump which uses a stepper motor in conjunction with an n-line cassette to meter IV fluids through a dedicated intravenous administration set that is also manufactured and distributed by Abbott Laboratories. The user interface of the infusion pump allows the user to program fluid delivery through a variety of weight and

**Proposed Device Description:** (cont'd)

medication based units such as micrograms/kg/hour, grams/hr and other delivery specifications.

An individual pump can accurately control the delivery of fluid from two input sources out to a single infusion line. The Abbott Plum A+3 infusion pump allows for six lines in and three lines out. While identical, each pump operates independently from the others and must be programmed separately. Each pump is uniquely labeled and numbered and differentiated by color of the center unit.

The proposed device includes a nurse call function that provides for remote monitoring in the case of alarm activation. A computer data port is provided that allows for an exchange of data from the pump to host computers in the healthcare facility. The display on each pump provides visible indication of several functions including active pump operations, alarm and program status and the parameters of fluid flow.

Each pump can be used for standard, piggyback, or concurrent fluid delivery.

**Statement of Intended Use:**

The Plum A+3 Multichannel Infusion Pump will be used to administer fluids into a patient's vascular system. The pump is intended for use in parenteral, enteral and epidural therapies and the administration of whole blood and blood products.

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

**Summary of Technological Characteristics of New Device Compared to Predicate Device**

The proposed pump has similar design, materials of construction, components, labeling and manufacturing process as the currently marketed Abbott Plum A+ Infusion Pump.

The subject and predicate devices have identical indications for use. Abbott proposes to modify the predicate device by placing three identical pumps into a single enclosure. The proposed device will utilize a single bar code wand and a single AC power source as opposed to three individual components for each pump. These differences do not raise new issues of safety and effectiveness.

**Discussion and Conclusions from Nonclinical Tests:**

Data regarding the functional performance of the proposed Abbott Plum A+3 Multichannel Infusion Pump has been generated and reviewed. The results of testing conducted to verify and validate 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

MAY 14 2002

Mr. Frank Pokrop
Abbott Laboratories
200 Abbott Park Road
Dept. 0389, Bldg. J-45
Abbott Park, Illinois 60064-6133

Re: K021350
Trade/Device Name: Abbott Plum A+3™ Multichannel Infusion Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: April 26, 2002
Received: April 29, 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) 594-4618Additionally, 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,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Attachment 3

## Indications for Use Statement

**510(k) Number** (if known)

K 02 1350

**Device Name:**

Abbott Plum A+3™ Multichannel Infusion Pump

**Indications For Use:**

Abbott Plum A+3™ Multichannel 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_____

Patricia Cucente

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021350