AUG 19 2003

K031566

510(k) Summary of Safety and Effectiveness

Submitted by:

Jennifer M. Paine
Manager, Regulatory Affairs
Baxter Healthcare Corporation
Medication Delivery
Rte. 120 and Wilson Road
Round Lake, IL 60073

Name/Classification of Device:

Infusion Pump/ Class II, 80MEA – 21 CFR 880.5725

Trade Name:

Syndeo PCA Syringe Pump

Predicate Devices:

PCA II Syringe Infusion Pump
Ipump Pain Management System

Statement of Intended Use:

The Syndeo PCA Syringe Pump is designed for the controlled delivery (continuous, intermittent, and continuous plus intermittent) of analgesic, sedative, and anesthetic solutions through clinically acceptable routes of administration including intravenous, subcutaneous, spinal (or intrathecal), epidural (or subarachnoid), and for regional anesthesia applications.

The Syndeo PCA Syringe Pump is appropriate for use in hospital or alternate medical site environments, but it is not intended for use in homecare settings.

The Syndeo PCA Syringe Pump is not indicated for use with blood or blood products.

Device Description:

The Syndeo PCA Syringe Pump consists of a syringe infusion pump with locking cover, and a PCA button for delivery of bolus doses of medication upon request. The pump accommodates 60 mL plastic syringes or 50 mL prefilled syringes. The pump can communicate with wireless accessories such as commercially available infrared printers or computing tools with device communications that are compatible with the Palm Operating System.

The Syndeo pump is capable of continuous, intermittent, or continuous plus intermittent infusion of small volumes of medications, following standard patient-request PCA regimens. The pump operates on 4 D-size alkaline batteries or the

optional AC rechargeable pack. The pump uses microprocessor electronics for control of all functions. A large, color touch-screen display provides a user-friendly graphic user interface (GUI), and simple programming steps that lead the operator through programming. As an added safety feature, the pump employs a variety of sensors to ensure appropriate syringe loading and door closure prior to allowing initiation of infusion.

Summary of Technological Characteristics of New Device to Predicate Devices:

The new and predicate devices have similar materials and basic design. The new device uses a touchscreen, color display and wireless communications technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 2003

Ms. Jennifer M. Paine
Manager, Regulatory Affairs
Baxter Healthcare Corporation
7511 114th Avenue North
Largo, Florida 33773

Re: K031566
Trade/Device Name: Syndeo PCA Syringe Pump
Regulation Number: 880. 5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEA
Dated: May 16, 2003
Received: May 19, 2003

Dear Ms. Paine:

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 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,

Susan Runner

Susan Runner, DDS, MA
Interim 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): _____

Device Name: Syndeo PCA Syringe Pump

Indications For Use:

The Syndeo PCA Syringe Pump is designed for the controlled delivery (continuous, intermittent, and continuous plus intermittent) of analgesic, sedative, and anesthetic solutions through clinically acceptable routes of administration including intravenous, subcutaneous, spinal (or intrathecal), epidural (or subarachnoid), and for regional anesthesia applications.

The Syndeo PCA Syringe Pump is appropriate for use in hospital or alternate medical site environments, but it is not intended for use in homecare settings.

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(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)

(Optional Format 1-2-96)

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

510(k) Number: K031564