JUN 2 5 2004

510(k) Summary of Safety and Effectiveness

K041191

Submitted by:

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

Name/Classification of Device:

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

Trade Name:

Colleague Volumetric Infusion Pump
Colleague CX Volumetric Infusion Pump
Colleague 3 Volumetric Infusion Pump
Colleague 3CX Volumetric Infusion Pump

Predicate Devices:

Colleague Volumetric Infusion Pumps

Statement of Intended Use:

Colleague Volumetric Infusion Pumps are electronic infusion pumps indicated for continuous or intermittent delivery of solutions through clinically acceptable routes of administration such as intravenous (IV), intra-arterial (IA), subcutaneous, epidural or irrigation of fluid spaces.

Device Description:

Colleague pumps use a shuttle and valve control system mechanism to provide accurate, continuous infusions. Colleague provides continuous infusion and combined modes of operation. The pumps have configurable input parameters, which allow institutions to pre-select which modes of operation will be available to users and which units of measure will be used for data entry. Baxter Healthcare proposes to modify the Colleague family of infusion pumps with the addition of new software features to expand the Colleague Guardian feature and to further enhance the safety of the device.

Summary of Technological Characteristics of New Device to Predicate Devices:

A comparison of the technological characteristics of the Colleague pump to the predicate devices has been performed. The results of this comparison demonstrate that the Colleague pump is equivalent to the marketed predicate device in technological characteristics.

Performance Data:

The performance data indicate that the device will meet specified requirements and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 5 2004

Ms. Amy Giertych
Director, Global Regulatory Affairs
Baxter Healthcare Corporation
Medication Delivery
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

Re: K041191
Trade/Device Name: Colleague Volumetric Infusion Pumps
Regulation Number: 880.5725
Regulation Name: Infusion Pumps
Regulatory Class: II
Product Code: FRN
Dated: May 5, 2004
Received: May 6, 2004

Dear Ms. Giertych:

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,

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): K041191

Device Name: Colleague Volumetric Infusion pumps

Indications For Use:

Baxter Colleague Infusion Pumps are designed to meet the fluid delivery needs of today's evolving health care environment. These pumps can be utilized for continuous or intermittent delivery through clinically acceptable routes of administration such as intravenous (IV), intra-arterial (IA), subcutaneous, epidural or irrigation of fluid spaces applications.

Fluid delivery applications include:

- parenteral fluids, drugs and electrolytes (e.g. cardiovascular drugs, antibiotics, anesthetics, analgesics, chemotherapy agents, total parenteral nutrition products, lipids, solutions for irrigation procedures, etc.); and
- whole blood and blood products.

Colleague Infusion Pumps are designed to travel the continuum of care, following the patient into a variety of care areas, including, but not limited to:

- Hospital:
  - General Floor
  - Medical/Surgical
  - Critical/Intensive Care Areas
  - Pediatrics/Neonatal
  - Labor/Delivery/Post Partum
  - OR/Anesthesia
  - Post Anesthesia/Recovery
  - Cardiac Cath Lab
  - Emergency Room
  - Burn/Trauma Units
  - Oncology
- Mobile Intensive Care
- Nursing Homes
- Homecare*
- Blood Centers
- Nuclear Medicine
- Hospice
- Subacute Facilities
- Outpatient/Surgical Centers
- Long Term Care

*Colleague and Colleague CX pumps only.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Irene Nawrocki for ADW 6/24/04
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041191