510(k) SUMMARY
Colleague® Pump Syringe Adapter Set

Submitted by:

Linda Coleman
Manager, Regulatory Affairs
Baxter Healthcare Corporation
I.V. Systems Division
Rte. 120 and Wilson Road
Round Lake, IL 60073

Date Prepared:
August 20, 1998

Proposed Device:
Colleague® Pump Syringe Adapter Set

Predicate Devices:
Baxter Solution Set with Microbore Tubing
Imed Vented Gemini® Syringe Set

Proposed Device Description:
The Colleague® Pump Syringe Adapter Set will be used to administer fluids from a standard syringe source container to a patient's vascular system using the Colleague® volumetric infusion pump. The only design difference between the proposed set and other Baxter IV administration sets is the container attachment mechanism which will allow the set to be directly connected to a syringe. This mechanism is an injection molded component which provides a female luer-lock attachment (syringe adapter) and a means for air inlet into the syringe (i.e., vent cap). Therefore, as air enters the syringe, fluid delivery is allowed through the Colleague® Pump Syringe Adapter Set.

Statement of Intended Use:

The Colleague® Pump Syringe Adapter Set will be used to administer fluids from a container to a patient's vascular system using an electronic infusion device.

Summary of Technological Characteristics of New Device to Predicate Devices

The proposed set has the same design as the currently marketed Baxter Solution Set with Microbore Tubing with the exception of the container attachment mechanism and fewer set components. The container attachment mechanism is similar to that used on the currently

marketed Imed Vented Gemini® Syringe Set. The solution contact materials used in the proposed device were previously tested and used in other Baxter devices for similar IV solution administration applications.

Discussion of Nonclinical Tests and Referenced Studies Reported in Published Literature

Data regarding the functional performance of the proposed Colleague® Pump Syringe Adapter Set have been generated and submitted. The data indicate that the proposed set meets or exceeds all functional requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 4 1998

Ms. Linda Coleman
Manager, Regulatory Affairs
Baxter Healthcare Corporation
I.V. Systems Division
Route 120 and Wilson Road
Round Lake, Illinois 60073

Re: K982672
Trade Name: Colleague® Pump Syringe Adapter Set
Regulatory Class: II
Product Code: FPA
Dated: July 30, 1998
Received: July 31, 1998

Dear Ms. Coleman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

S. Nutman 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

Indication for Use

510(k) Number: Not Available

Device Name: Colleague® Pump Syringe Adapter Set

Indication for Use:

The Colleague® Pump Syringe Adapter Set will be used to administer fluids from a container to a patient's vascular system using an electronic infusion device.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K982672

Prescription Use ✓
(Per 21 CFR 801.109)