K 974571

## 510(k) SUMMARY

MAY 21 1998

Solution Administration Sets with Capped Luer Activated Valve

**Submitted by:**

Mary Ellen Snyder
Baxter Healthcare Corporation
I.V. Systems Division
Rte. 120 and Wilson Road
Round Lake, IL 60073

**Date Prepared:**
December 5, 1997

**Proposed Device:**
Solution Administration Sets with Capped Luer Activated Valve

**Predicate Device:**
Abbott I.V. Sets with Capped Reflux Valve Port

**Proposed Device Description:**

The subject of this submission is a capped luer activated valve which Baxter intends to incorporate into currently marketed solution sets. The capped luer activated valve will replace the Y-injection site on the set for continuous or intermittent fluid administration or the withdrawal of fluids. The normally closed valve is opened by removing the cap and inserting a standard male luer adapter such as on syringes or sets to the female end of the valve. The valve automatically closes when the male luer is disconnected. The valve is intended to be capped when not in use.

**Statement of Intended Use:**

Baxter solution administration sets with capped luer activated valve are intended for use with a vascular access device for the administration of drugs and solutions. The capped luer activated valve will replace the Y-injection site on the set. The valve can be connected to standard male luer adapters (e.g., syringes or sets), for continuous or intermittent fluid administration or the withdrawal of fluids.

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

Baxter sets with the proposed valve are identical to currently marketed Baxter sets except for the change from a Y-injection site to a capped T-shaped luer activated valve. All other components of the solution administration sets remain unchanged. The T-shaped valve is very similar to the Y-shaped valve contained in currently marketed Abbott IV solution sets. The main difference between the proposed T-shaped valve and the currently marketed Y-shaped valve are the material and geometry of the valve housing.

**Discussion of Nonclinical Tests and Referenced Studies Reported in Published Literature**

Data regarding the functional performance of the proposed capped luer activated valve have been generated. A description of the functional testing along with test results has been provided. The data indicate that the proposed valve meets or exceed all functional requirements and support its suitability for use in Baxter solution administration sets.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

MAY 21 1998

Re: K974571
Trade Name: Solution Administration Set with Capped Luer Activated valve
Regulatory Class: II
Product Code: FPA
Dated: May 12, 1998
Received: May 13, 1998

Dear Ms. Synder:

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,

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

Enclosure

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510(k) Number: Not Available

Device Name: Solution Administration Sets with Capped Luer Activated Valve

Indication for Use:

Baxter solution administration sets with capped luer activated valves are intended for use with a vascular access device for the administration of drugs and solutions. The capped luer activated valve will replace the Y-injection site on the set. The valve can be connected to standard male luer adapters (e.g., syringes or sets), for continuous or intermittent fluid administration or the withdrawal of fluids.

Patricia Cucante
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974571

Prescription Use ✓
(Per 21 CFR 801.109)