K971701

JUN - 6 1997

510(k) SUMMARY

Continu-Flo® Solution Sets with Modified Check Valve

Submitted by:

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I.V. Systems Division
Rte. 120 and Wilson Road
Round Lake, IL 60073

Date Prepared:
May 7, 1997

Proposed Device:
Continu-Flo® Solution Sets with Modified Check Valve

Predicate Devices:
Continu-Flo® Solution Sets with Check Valve

Proposed Device Description:

The proposed Continu-Flo® sets contain a check valve which prevents backflow of solution from the secondary medication container into the primary container during administration of secondary medication. The current check valve is a disc valve and is positioned in the set tubing between the drip chamber and Y-injection site. The new check valve is a duck bill valve and is positioned inside the Y-injection site housing of the set.

There is one material in the proposed check valve design which is new to Baxter devices. The valve itself will be formulated from a new polyisoprene material. The materials used on the proposed check valve cap and housing, are the same as those in use on the current check valve body and Y-injection site housing on Continu-Flo® solution sets. All other materials in the solution sets remain unchanged.

Statement of Intended Use:

Continu-Flo® solution sets with the proposed check valve have the same intended use as the currently marketed sets. The intended use of these sets is the administration of fluids from a container to the patient's vascular system. Continu-Flo® sets contain a check valve which prevents backflow of solution from the secondary medication container into the primary container during the administration of secondary medication.

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Summary of Technological Characteristics of New Device to Predicate Devices

The proposed solution sets are identical to currently marketed Continu-Flo® Solution Sets with Check Valve, previously cleared under K881052, except for the design and location change of the check valve component. The current check valve is a disc valve and is positioned in the set tubing between the drip chamber and Y-injection site. The proposed check valve is a duck bill valve and is positioned inside the Y-injection site housing of the set. All other components of the solution administration sets remain unchanged.

Discussion of Nonclinical Tests and Referenced Studies Reported in Published Literature

The biological and chemical reactivity of the new polyisoprene material have been assessed using biological methods specified in ISO Standard 10993-1 and USP Physicochemical tests. The material was found to be acceptable for its intended use.

Data regarding the functional performance of the proposed check valve have been generated. A description of the functional testing along with test results is provided. The data indicate that the proposed check valve meets or exceeds all functional requirements and support its suitability for use in Continu-Flo® sets.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Mary Ellen Snyder
Manager, Regulatory Affairs
Baxter Healthcare Corporation
Route 120 And Wilson Road
Round Lake, Illinois 60073

Re: K971701
Trade Name: Continu-Flo® Solution Sets with Modified Check Valve
Regulatory Class: II
Product Code: FPA
Dated: May 07, 1997
Received: May 08, 1997

Dear Ms. Snyder:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

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) 594-4618. 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" (21 CFR 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 at (301) 443-6597.

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

510(k) Number: Not Available

Device Name: Continu-Flo® Solution Sets with Modified Check Valve

Indication for Use:

Continu-Flo® solution sets with the proposed check valve have the same intended use as the currently marketed sets. The intended use of these sets is the administration of fluids from a container to the patient's vascular system. Continu-Flo® sets contain a check valve which prevents backflow of solution from the secondary medication container into the primary container during the administration of secondary medication.

(Division Sign-Off) Patricia Cucanta
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K971701

Prescription Use ✓
(Per 21 CFR 801.109)

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