K983294

NOV 3 1998

510(k) SUMMARY

Modified All-In-One™ Container

Submitted by:

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

Date Prepared:
September 18, 1998

Proposed Device:
Modified All-In-One™ Container

Predicate Device:
All-In-One™ Container

Proposed Device Description:
The All-In-One™ Container is an empty, EVA container intended for use in the compounding and storage of parenteral nutrition solutions prior to and during intravascular administration to a patient. The container will be marketed in sizes ranging from 150 mL to 4000 mL. The proposed container is similar to Baxter Healthcare Corporation's currently marketed All-In-One™ Container cleared on June 10, 1994 under K932477.

There is one solution contact material in the proposed All-In-One™ Container which is new to Baxter. It is an ethylene vinyl acetate (EVA) film which is used to fabricate the container body. The other solution materials used in the proposed device were previously tested and used in other Baxter devices for similar IV container applications.

Statement of Intended Use:

The All-In-One™ Container is intended for use in the compounding and storage of parenteral nutrition solutions prior to and during intravascular administration to a patient.

Summary of Technological Characteristics of New Device to Predicate Devices

Except for the EVA film used to construct the body of the modified All-In-One™ Container, the proposed container is identical with respect to materials, components and design to the existing All-In-One™ Container described in K932477. Like the existing product, the proposed All-In-One™ Container will be used in the compounding and storage of parenteral nutrition solutions prior to and during intravascular administration to a patient.

Discussion of Nonclinical Tests and Referenced Studies Reported in Published Literature

The biological and chemical reactivity of the new solution contact material have been assessed using biological methods specified in ISO Standard 10993-1 and USP physicochemical tests described in General Chapter <661> of USP 23. The material was found to be acceptable for its intended use.

Data regarding the functional performance of the proposed All-In-One™ Container have been generated and submitted. The data indicate that the proposed All-In-One™ Container meets or exceeds all functional requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K983294
Trade Name: All-In-One™ Container CAT#'s 2B8114, 2B8124, 2B8134, 2B8144
Regulatory Class: II
Product Code: KPE
Dated: September 18, 1998
Received: September 21, 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,

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: No: Available

Device Name: All-In-One™ Container

Indication for Use:

The All-In-One™ Container is intended for use in the compounding and storage of parenteral nutrition solutions prior to and during intravascular administration to a patient.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983294