K032789

OCT - 9 2003

Supporting Clinical Engineering Worldwide

510(k) Summary

Submitter Information:

American IV Products, Inc.
7485 Shipley Avenue
Hanover, MD 21076

Contact:

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Date Prepared:

August 22, 2003

Product Name:

Classification Name: Volumetric Infusion Pump Door Assembly
Common Name: Replacement Pump Head Door Assembly, P1
Replacement Pump Head Door Assembly, P2
Proprietary Name: Replacement Pump Head Door Assembly, P1
Replacement Pump Head Door Assembly, P2

Predicate Device:

These door assemblies are equivalent to the legally marketed door assemblies in the following devices:
Baxter Flo-Gard® 6201 – K915522
Baxter Flo-Gard® 6301 – K915523

Description:

AIV's pump door assemblies are replacements for similar doors manufactured by Baxter Healthcare Corporation for their Flo-Gard® 6201 and Flo-Gard® 6301 Volumetric Infusion Pumps. The door is part of a linear peristaltic pumping mechanism. The door assemblies are intended to be direct replacement for the predicate device door assembly.

Intended Use:

These devices are intended to be used as replacement door assemblies for Baxter Flo-Gard® 6201 and Baxter Flo-Gard® 6301 volumetric infusion pumps, for use to deliver drug solutions, enteral feedings and blood.

Comparison to Predicate Device:

	AIV	Baxter
Intended use	Pump head door assembly for use in a volumetric infusion pump that uses a linear peristaltic pumping mechanism.	Same
Design	A latching plastic and metal door that contains a spring mounted pump backing plate	Same
Materials	Molded plastic door "blank" that contains aluminum and brass inserts, an aluminum back plate, spring loaded nylon constructed pump backing plate, plastic latch handle with stainless steel pin, bronze latch bushing, and rubber bumpers.	Same
Performance	Flow volume within 7% of programmed volume for a program flow rate	Same
Where used	Hospital	Same
Biocompatibility	Not intended for contact with patient skin or contact with operator/programmer skin for prolonged periods of time.	Same
Sterility	Non-sterile	Same

Performance Data and Conclusions:

- AIV door assembly components are made from similar materials to the predicate device component materials.
- AIV component design is equivalent to predicate device component design.
- AIV assembly design is equivalent to predicate device assembly design.
- Bench Testing demonstrates that the AIV devices perform as intended and are equivalent to predicate device assemblies.
- Bench testing demonstrates that the AIV door "blank" component of a door assembly when used in place of a predicate device door "blank" component in an otherwise complete predicate device door assembly, the hybrid assembly performs as intended and is equivalent to predicate device door assembly.
- These devices do not raise new issues of safety and effectiveness, nor do they alter the fundamental technology of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 9 2003

Mr. Gregory Falk
Engineering Manager
American IV Products, Incorporated
7485 Shipley Avenue
Hanover, Maryland 21076

Re: K032789
Trade/Device Name: Replacement Pump Head Door Assembly, P1, and P2
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: August 22, 2003
Received: September 8, 2003

Dear Mr. Falk:

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

Statement of Indications for Use

510(k) # K032789
Device Name: Replacement Pump Head Door Assembly, P1
Replacement Pump Head Door Assembly, P2

Indications for use:

These devices are intended to be used as replacement door assemblies for Baxter Flo-Gard® 6201 and Baxter Flo-Gard® 6301 volumetric infusion pumps, for use to deliver drug solutions, enteral feedings and blood.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucento

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032789