K070384

Argon
Medical Devices

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510(k) Summary

MAR 2 9 2007

Owner: Argon Medical Devices
Address: 1445 Flat Creek Road
Athens, TX 75751
Contact Person: Amy Windham
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Date of Summary: February 8, 2007

Device Information

Trade Name	Argon Continuous Flush Device
Common Name	Continuous Flush Device
Classification Name/Product Code	Catheter, Continuous Flush / 870.1210/KRA

Predicate Device
Edwards Uniflow Flush Device and American Pharmaseal Blood Pressure Transducer including a continuous flush device are the predicate devices for the Argon Continuous Flush Device. The 510(k) for the original Edwards Uniflow Flush Device is K792141, filed by the Edwards Critical Care Division of Baxter Healthcare. K832907 was filed by American Pharmaseal, also a Baxter Edwards company, for a blood pressure transducer that included a continuous flush device. The flush device included as an integral part of the American Pharmaseal transducer is also sold individually by Edwards Lifesciences. This device was used for the bench testing.

Description of the Device
Invasive physiological pressure monitoring requires a number of components that include an IV administration set, a pressure transducer, a monitoring line and a catheter. Because of the potential for clot formation over the course of physiologic monitoring, a continuous flush device can be included in these systems for slow flush of the monitoring line. This minimizes the possibility that blood clots will form within the catheter and at the catheter tip. The Argon Continuous Flush Device is a slow flush device that is intended to be used with the components identified above for slow and continuous flushing of indwelling lines to minimize the formation of clots that would interfere with monitoring integrity.

The Argon Continuous Flush Device is manufactured in two distinct configurations, a 3 ml/hr flow rate device and a 30 ml/hour flow rate device. The design difference which results in continuous flow rates of 3 ml/hr and 30 ml/hr for each of the two models of devices is achieved by the diameter of a laser-drilled flow control orifice in each unit.

The orifice diameter is predefined for each version to correlate to the desired output flow rate. The two devices are distinguished from one another by the color of the flush device cap. The 3 ml/hr continuous flush device has a clear cap and the 30 ml/hr continuous flush device has a yellow cap.

Both devices are connected to an IV administration system including a pressurized bag of saline that typically is heparinized. Applied pressure from the bag (300 mmHg) initiates the flow through the IV administration set and the flush device. The slow flow prevents over-infusion, and minimizes clot formation. The "fast flush" feature of the device assists in priming and removing bubbles from the lines or catheters and supplying a fast flow of intravenous fluid to the patient to assess the integrity of the entire monitoring system. This feature is actuated by squeezing the tabs on either side of the device or by pulling up the pull tab on the top of the device.

Intended Use of the Device
Argon's Continuous Flush Device is intended for use in invasive physiological pressure measurements which require continuous regulated flow to maintain catheter patency.

Technological Characteristics Compared to Predicate Device
Both the Argon Continuous Flush Device and Edwards Uniflow Flush Device are manufactured using industry standard plastics and silicone. Specific material information for the Argon Continuous Flow Device is detailed in another section of the 510(k). Design characteristics of each device are very similar. Both Argon's and Edwards' device includes a squeeze actuator and a pull tab for fast flush. Configurations vary with female/male or glue sites to connect to a transducer or monitoring line. Each device has a specified orifice diameter that allows either a nominal 3 ml/hr or a nominal 30 ml/hr fluid flow.

Performance Summary
Non-clinical performance data demonstrates that the Argon Continuous Flush Device performed in an equivalent manner to the predicate and is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Argon Medical Devices Inc.
c/o Ms. Amy Windham
Quality Manager
1445 Flat Creek Road
Athens, TX 75751

MAR 2 9 2007

Re: K070384
Argon Continuous Flush Device
Regulation Number: 21 CFR 870.1210
Regulation Name: Catheter, Continuous Flush
Regulatory Class: II (two)
Product Code: KRA
Dated: February 8, 2007
Received: February 9, 2007

Dear Ms. Windham:

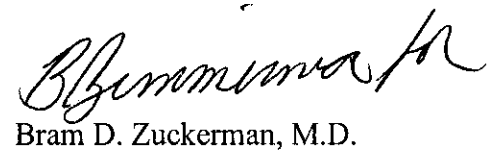
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Continuous Flush Device

Indications for Use:

For use in invasive physiological pressure measurements which require continuous regulated flow to maintain catheter patency.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070384