K032962

OCT 2 9 2003

510(k) Summary

Submitter:	ARROW International, Inc. 2400 Bernville Road Reading, PA 19605-9607 USA
Contact person:	Elizabeth Price, Regulatory Associate Phone: 610-378-0131, ext. 3220 Fax: 610-374-5360 Email: elizabeth.price@arrowintl.com
Date summary prepared:	9/22/03
Device trade name:	MAC™ 3 Lumen Central Venous Access Kit with ARROWg+ard Blue® Antimicrobial Surface.
Device common name:	Catheter introducer; intravascular catheter
Device classification name:	DYB, Class II, 21 CFR 870.1340, Catheter, introducer, short term. FOZ, Class II, 21 CFR 880.5200, Catheter, Intravascular, short term
Legally marketed devices to which the device is substantially equivalent:	Arrow MAC™ 2 Lumen Central Venous Access Kit with ARROWg+ard Blue® Antimicrobial Surface (K011761). Baxter Multiple-Lumen Access Products (K981909).
Description of the device:	The Arrow MAC™ with ARROWg+ard Blue® is a venous access catheter with the functionality of three segregated internal pathways. The hemostasis valve and distal lumen can accommodate a thermodilution catheter, or similar device, 7 to 8 Fr in size while the remaining space is utilized as a flow lumen through the distal port.
Intended use of the device:	The Arrow Three-Lumen Central Venous Access device permits venous access and catheter introduction to the central circulation. The ARROWg+ard antimicrobial surface is intended to help provide protection against access device-related infections. It is not intended to be used as a treatment for existing infections nor is it indicated for long-term use.
Technological characteristics:	The proposed device has the same technological characteristics as the predicate device(s).

Performance tests:	Tests were performed to demonstrate substantial equivalence in the following areas: - Flow rate - Leak test - Tensile test - Fatigue test - Flex modulus test
Conclusions:	The results of the laboratory tests demonstrate that the device is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 9 2003

Ms. Elizabeth Price
Regulatory Affairs
ARROW International, Incorporated
2400 Bernville Road
Reading, Pennsylvania 19605

Re: K032962
Trade/Device Name: MAC™ 3 Lumen Central Venous Access Kit with ARROWg+ard Blue® antimicrobial surface
Regulation Number: 880.5200, 870.1340
Regulation Name: Intravascular Catheter, Catheter Introducer
Regulatory Class: II
Product Code: FOZ, DYB
Dated: September 22, 2003
Received: September 29, 2003

Dear Ms. Price:

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K032962

Device Name: MAC™ 3 Lumen Central Venous Access Kit with ARROWg+ard Blue® antimicrobial surface

Indications for Use: The Arrow Central Venous Access Product permits venous access and catheter introduction to the central circulation. The ARROWg+ard Blue® antimicrobial surface is intended to help provide protection against access device-related infections. It is not intended to be used as a treatment for existing infections nor is it indicated for long-term use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cuccia

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

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