MAR - 5 2004

510(k) Summary

Submitter:	ARROW International, Inc. 2400 Bernville Road Reading, PA 19605-9607 USA
Contact person:	Brandon Epting, Regulatory Affairs Associate Phone: 610-378-0131, ext. 8498 Fax: 610-374-1160 Email: brandon.epting@arrowintl.com
Date summary prepared:	February 3, 2004
Device trade name:	Integral hemodialysis catheter
Device common name:	Chronic hemodialysis catheter
Device classification name:	MSD, Class III, 21 CFR 876.5540, Catheter, Hemodialysis, Implanted
Legally marketed devices to which the device is substantially equivalent:	Arrow Cannon Catheter (K010399).
Description of the device:	The Arrow integral hemodialysis catheter consists of a double lumen catheter with a molded juncture hub and two extension lines. This allows the catheter tip to be precisely positioned within the vein, similar to single lumen, dual catheters.
Intended use of the device:	The Arrow® integral catheter is indicated for use in attaining long-term vascular access for hemodialysis and apheresis. The integral catheter is inserted percutaneously and is preferentially placed into the internal jugular (IJ) vein. Alternately, this catheter may be inserted into the subclavian vein although the jugular vein is the preferred site. Catheters greater than 40 cm are intended for femoral vein insertion. The integral catheter is intended for use in adult patients.
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 tests - Leak tests - Tensile tests - Flex tests - Chemical compatibility tests - Biocompatibility tests - Hemolysis tests
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

MAR - 5 2004

Mr. Brandon Epting
Regulatory Affairs Associate
ARROW® INTERNATIONAL
P.O. Box 6306
READING PA 19610

Re: K040260
Trade/Device Name: Integral chronic hemodialysis catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: February 3, 2004
Received: February 4, 2004

Dear Mr. Epting:

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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 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 (21 CFR Part 807); 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 the labeling regulation, please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K040260

Device Name: Integral hemodialysis catheter

Indications for Use: The Arrow® integral catheter is indicated for use in attaining long-term vascular access for hemodialysis and apheresis. The integral catheter is inserted percutaneously and is preferentially placed into the internal jugular (IJ) vein. Alternately, this catheter may be inserted into the subclavian vein although the jugular vein is the preferred site. Catheters greater than 40 cm are intended for femoral vein insertion. The integral catheter is intended for use in adult patients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040260

Prescription Use ✓ K040260
(21 CFR 801.109)