K022662 Page 1 of 1

MAY - 9 2003

510(k) Summary

Submitter of 510(k):	Arrow International, Inc. 2400 Bernville Road Reading, PA 19605 Phone: 610/478-3137 Fax: 610/478-3172
Contact Person:	Tom Nickel
Date of Summary:	April 30, 2003
Trade Name:	Hemodialysis Catheter, 55 cm.
Classification Name:	Catheter, Hemodialysis, Implanted
Predicate Device:	Diatek Cannon-Cath

Intended Use:

The Arrow Diatek™ Cannon Catheter™ is indicated for use in attaining long-term vascular access for Hemodialysis and Apheresis. The Cannon Catheter™ is inserted percutaneously and is preferentially placed into the internal jugular vein. Alternately, this catheter may be inserted into subclavian vein, although the jugular vein is the preferred site. Catheters greater than 40 cm are intended for femoral vein insertion. The Cannon Catheter™ is intended for use in adult patients.

Device Description

The Arrow Diatek Cannon Catheter consists of a double-lumen catheter with a detached connector assembly. This allows the catheter tip to be precisely placed within the vein, similar to single lumen, dual catheters. After the catheter has been positioned, the proximal end of the catheter is tunneled retrograde to the exit site. The connector assembly is then fastened to the proximal end of the catheter using a compression sleeve and compression cap.

Testing

The catheter has been physically tested by both internal and outside laboratories for a wide range of criteria as well as in comparison to the predicate device. Examples include dimensional comparisons, tensile tests, pressure/flow characteristics, ISO luer conformance, ISO 10555-1 conformance, flex tests, and recirculation.

2003045

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2003

Mr. Thomas D. Nickel
Vice President Regulatory Affairs and Quality Assurance
Arrow International
2400 Bernville Road
READING PA 19605

Re: K022662
Trade/Device Name: Arrow Diatek™ Cannon Cath™, Model CC5500
(15 Fr. 55cm length for femoral implant)
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: March 4, 2003
Received: March 6, 2003

Dear Mr. Nickel:

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-__. 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,

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

Enclosure

510(k) number K022662

Device Name: Diatek Cannon Cathater, 55 cm. length

Indications for Use:

The Arrow Diatek™ Cannon Catheter™ is indicated for use in attaining long-term vascular access for Hemodialysis and Apheresis. The Cannon Catheter™ is inserted percutaneously and is preferentially placed into the internal jugular vein. Alternately, this catheter may be inserted into subclavian vein, although the jugular vein is the preferred site. Catheters greater than 40 cm are intended for femoral vein insertion. The Cannon Catheter™ is intended for use in adult patients.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The_Counter Use _____

(Optional Format 1-2-96)

2003028

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022662