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K991431
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Section 5 – 510(k) Summary

a. Submitter

ARROW International, Inc.
2400 Bernville Road
Reading, PA 19605

Contact Person: Thomas D. Nickel
Vice President, Regulatory Affairs and Quality Assurance
610-478-3137

Date summary prepared: April 22, 1999

b. Device

Trade Name: Two-Lumen Hemodialysis Catheterization Kit

Common Name: Hemodialysis Catheter

Classification Name: Blood Access Device and Accessories (non-implanted version).

c. Legally marketed device to which the device is substantially equivalent

The device is substantially equivalent to the current legally ARROW 12 Fr Large-Bore Dual Lumen Hemodialysis Catheterization Kit. Moreover, the subject device also has similar mechanical properties compared to the legally marketed Vas~Cath® Niagara™ Catheter.

d. Description of device

1. 14 Fr Two-Lumen Hemodialysis Catheter

The device is a dual-lumen, polyurethane catheter, 14 French in size, with two independent non-communicating lumens, extension lines, Luer hubs and extension line clamps. Each lumen exits at the distal end of the catheter through individual ports spaced at a given distance apart. A soft tip that is more pliable than the catheter body is grafted onto the distal tip of the catheter. At the proximal end of the juncture hub the lumens are connected to clear separate extension lines. Each extension line contains either a red or blue clamp. The colored clamps indicate arterial flow (outflow) or venous flow (inflow). Also, centimeter markings are placed along the length of the indwelling catheter body to facilitate proper positioning. The catheter is available in a length of 16cm and is identical in appearance and function to the other manufactured catheter products aforementioned in section 3b. Moreover, the ARROW 14 Fr Hemodialysis Catheter is also identical to the ARROW predicate catheter with the exception of French size.

2. 14 Fr Hemodialysis Two-Lumen Catheterization Kit

An ARROW 14 Fr Hemodialysis Two-Lumen Catheterization Kit consists of a dual-lumen catheter packaged with various accessory components that are required during catheterization. These components include combinations of the following: spring wire guides, dilators, introducer needles, catheter over needle assemblies, syringes, pressure transduction probes, scalpels, disposal cups and medication. Moreover, the kit also includes labeling information including instructions for use, contents sheet and various unit package labels. The contents of the kit are contained in tray and wrapped with in an absorbent cloth. The wrapped kit is then packaged into another tray and sealed with Tyvek lidstock. The complete trays are placed in shipping containers, labeled and sterilized.

e. Intended use of the device

The large-bore two-lumen catheter is indicated for temporary or short-term hemodialysis and apheresis. It may be inserted in the subclavian or femoral veins.

f. Technological characteristics

The device has the same exact technological characteristics as the predicate.

The performance tests included in the submission include:

1) Tensile tests
   a) Blue tip to catheter body
   b) Catheter body to juncture hub
   c) Extension lines to juncture hub
2) Flow rate test
3) Prime volume test
4) Flex fatigue
5) Recirculation
6) Kink test
7) Shelf-Life; mechanical age testing
8) Mechanical hemolysis

The results of the laboratory tests demonstrated that the device is safe, and as effective as the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 6 1999

Thomas D. Nickel
Vice President, Regulatory Affairs and Quality Assurance
Arrow International, Inc.
2400 Bernville Road
Reading, Pennsylvania 19605

Re: K991431
Trade Name: 14 Fr Two-Lumen Hemodialysis Catheterization Kit
Regulatory Class: II
Product Code: 78 MPB
Classification: 21 CFR §876.5540
Dated: April 22, 1999
Received: April 26, 1999

Dear Mr. Nickel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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 (the Act). You may, therefore, market the device, subject to the general controls provisions of 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 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/tray. 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 (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may

result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

FDA notes that your device will contain sutures for which you have provided evidence that the suture characteristics are not altered by the sterilization process used for the device. However, you should be aware of the following additional information regarding the inclusion of a suture as a component of your device:

1. The labeling, packaging and method of sterilization of the suture cannot be changed without prior notification, review and clearance by FDA.

2. The supplier of the sutures used in your device cannot be changed without prior notification, review and clearance by FDA.

In addition, we have determined that your device kit contains povidone-iodine ointment, povidone-iodine swabsticks, and lidocaine, which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your 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 and additionally 809 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general

information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K991431

Section 6 – Indications for use

Device name: 14 Fr. Two-Lumen Hemodialysis Catheterization Set

Indications for use:

The large-bore two-lumen catheter is indicated for temporary or short-term hemodialysis and apheresis. It may be inserted in the subclavian or femoral veins.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991431