SEP 14 2000

K993933

510(k) SUMMARY

Submitter:

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

Contact person:

Thomas D. Nickel
Vice President, Regulatory Affairs and Quality Assurance
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Date summary prepared:

September 14, 2000

Trade name:

Two-Lumen Hemodialysis Catheterization Kit with Blue FlexTip® ARROWg+ard Blue® Catheter for High Volume Infusions

Common name:

Two-lumen, short-term access central venous hemodialysis catheter

Classification name:

- Class II at 21 CFR 880.5200, Catheter, Intravascular, short term
- Class II at 21 CFR 876.5540, Catheter, Hemodialysis, non-implanted

Legally marketed devices to which the device is substantially equivalent:

- Antimicrobial multi-lumen central venous catheter (K900263)
- Arrow large-bore dual lumen hemodialysis kit (K895417)

Description of device:

The materials, construction, and manufacturing processes of both the legally marketed 12 Fr Hemodialysis Catheter and the 7 Fr ARROWg+ard Blue® antimicrobial multi-lumen central venous catheter have been integrated to generate the proposed device.

The proposed device is a dual-lumen, antimicrobial surface, polyurethane catheter, 12 Fr and 14 Fr in size, with two independent non-communicating lumens, extension lines, Luer hubs, and extension line clamps. 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 indicating arterial flow (outflow) or venous flow (inflow). Centimeter markings are placed along the length of the indwelling portion of the catheter body to facilitate proper positioning. The catheter is available in a length of 16cm, 20cm and 25cm.

The finished kit consists of the two-lumen, antimicrobial surface catheter packaged with various accessory components that are required during catheterization. These components include a combination of the following: spring wire guides, dilators, introducer needles, catheter over needle assemblies, syringes, pressure transduction probes, scalpels, disposal cups, and medication. The kit contains complete labeling

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including Instructions for Use, contents sheet, and unit package labels. The contents of the kit are configured in a tray and sealed with a Tyvek® lid. The complete trays are then placed in shipping containers and sterilized.

Intended use of the device:

The large-bore two-lumen catheter permits venous access to the central circulation for rapid fluid administration, temporary or acute hemodialysis, apheresis and hemofiltration. It may be inserted into the jugular, subclavian, or femoral veins.

The ARROWg+ard Blue® antimicrobial surface catheter helps provide protection against catheter-related infections resulting from microorganisms migrating the subcutaneous tract along the exterior surface of the catheter when used for infusion. Clinical data have not been collected that demonstrate the use of the ARROWg+ard Blue® antimicrobial surface in decreasing catheter-related infections in hemodialysis patients. The catheter 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 devices.

Performance tests:

The following performance tests are included in the submission.

- *In vitro* efficacy – zone of inhibition
- *In vitro* safety – elution profile
- Stability tests
- Biocompatibility tests

Conclusions:

The results of the laboratory tests demonstrate that the device is as safe as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2000

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

Re: K993933
12 Fr. and 14 Fr. Two-Lumen Hemodialysis Catheterization Kit with Blue FlexTip®
ARROWg+ard Blue® Antimicrobial Catheter for High Volume Infusions
Regulatory Class: II
21 CFR §876.5540/Product Code: 78 MPB
Dated: June 13, 2000
Received: June 16, 2000

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.

In addition, we have determined that your device kit contains povidone-iodine swab sticks, povidone-iodine ointment and lidocaine HCI 1%, 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,

for David A. Lyon

Daniel G. Schultz, M.D.
Captain, USPHS
Acting 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: K993933

Device Name: Two-Lumen Hemodialysis Catheterization Kit with Blue FlexTip® ARROWg+ard Blue® Antimicrobial Catheter for High Volume Infusions

Indications for Use: The large-bore two-lumen catheter permits venous access to the central circulation for rapid fluid administration, temporary or acute hemodialysis, apheresis and hemofiltration. It may be inserted into the jugular, subclavian, or femoral veins

The ARROWg+ard Blue® antimicrobial surface catheter helps provide protection against catheter-related infections resulting from microorganisms migrating the subcutaneous tract along the exterior surface of the catheter when used for infusion. Clinical data have not been collected that demonstrate the use of the ARROWg+ard Blue® antimicrobial surface in decreasing catheter-related infections in hemodialysis patients. The catheter is not intended to be used as a treatment for existing infections, nor is it indicated for long-term use.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993933

Prescription Use ✓
(Per 21 CFR 801.109)