K970864

510(k) SUMMARY - K970864

OCT 17 1997

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 - 10/16/97

Device:

Trade Name - Arrow-Howes™ Large Bore Multi-lumen central venous catheter

Common Name - Central venous catheter

Classification Name - Catheter, intravascular, 80FOZ, and 21 CFR 880.5200, Intravascular catheter

Legally marketed device to which the device is substantially equivalent:

Various Arrow central venous catheters; specifically K820648, K844080, K862056, and K895417

Description of device:

The device is a triple-lumen polyurethane catheter, 12 French in size, with three extension lines, luer hubs, and clamps. It is essentially the same in appearance and function to the Arrow multi-lumen predicate catheters except for the larger size to accommodate rapid fluid administration in emergency critical care situations in the hospital.

Intended use of the device:

The intended use and indications for use are comparable to the predicate devices, and appear below:

"Indications for use:
The large-bore multiple lumen catheter permits venous access to a central circulation for rapid fluid administration. It may be inserted into the jugular, subclavian, and femoral veins. The heparin coating on the catheter intended to decrease the incidence of thrombous formation associated with catheterization."

Technological characteristics:

The device has the same exact technological characteristics as the predicates, with the only difference being the larger size and accompanying greater fluid flow rates.

The performance tests included in the submission include:

1. Flow rate
2. Tensile test
3. Pressure leak test
4. Positive pressure burst test
5. Biocompatibility tests
6. Flex (fatigue) test

No clinical testing was performed.

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

97095

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. Thomas D. Nickel
Vice President, Regulatory Affairs and
Quality Assurance
Arrow International, Incorporated
3000 Bernville Road
Reading, Pennsylvania 19605

OCT 17 1997

Re: K970864
Trade Name: Arrow-Howes Large Bore Multi-Lumen Central Venous Catheters
Regulatory Class: II
Product Code: FOZ
Dated: July 21, 1997
Received: July 22, 1997

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 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. 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 such 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 requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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.

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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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K 970864 : Arrow-Howes™ Large Bore Multi-lumen Central Venous Catheters

Section 11 - Indications

The large bore multiple lumen catheter permits venous access to a central circulation for rapid fluid administration. It may be inserted into the jugular, subclavian, or femoral veins. The heparin coating on the catheter intended to decrease the incidence of thrombus formation associated with catheterization.

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X Prescription Use

Viola Hilliard for Catherine Cicenia

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K970864