FEB 13 1998

510(k) SUMMARY - K970229

ARROW TRANSSEPTAL SUPER ARROW-FLEX®
PERCUTANEOUS SHEATH INTRODUCER SET

Date: January 16, 1997
Submitted By: Thomas D. Nickel
Vice President, Regulatory Affairs and
Quality Assurance
Arrow International, Inc.
3000 Bernville Road
Reading, PA 19605
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Trade name

Arrow Transseptal Super Arrow-Flex® Percutaneous Sheath Introducer Set, consisting of the following:

- One radiopaque Super Arrow-Flex® sheath with integral side port/hemostasis valve, 3-way luer-lock stopcock and radiopaque marker band
- One vessel dilator

Common or classification name

The device was originally listed as Introducer, catheter, 74 DYB, and was subsequently classified in class II at CFR 870.1340, catheter introducer.

Common names are sheath introducer, percutaneous sheath introducer, catheter introducer, sheath, introducer, PSI.

Substantial equivalence

The device is substantially equivalent to the following legally marketed products:

1. Arrow Super Arrow-Flex® percutaneous sheath introducer sets
2. Bard Mullins transseptal catheter introducer set
3. Daig Fast-Cath™ transseptal introducer

This device is identical in construction to the Arrow predicate device except for a curved sheath and dilator, plus tip marker band.

Description:
The Arrow Transseptal Super Arrow-Flex Percutaneous Sheath Introducer Set consists of a long radiopaque wire-reinforced sheath and dilator with curved distal tips for positioning against the atrial septum.. The introducer sheath contains an integral hemostasis valve and side port with a three-way stopcock. The dilator accommodates a curved transseptal needle (18ga. needle for adults and 19ga. needle for pediatrics) and has a long gradual tapered tip that steps up to the OD for ease of insertion.

Indications for use:

The Arrow Transseptal Super Arrow-Flex Percutaneous Sheath Introducer Set is intended for use in the hospital catheterization laboratory for the percutaneous introduction of various cardiovascular devices into the left side of the heart through the interatrial septum.

The device has comparable technological characteristics to the predicate devices.

The nonclinical test results included in the submission showing comparable performance to the Bard predicate device are as follows:

1. Compatibility of sheath/dilator with the Brockenbrough needle assembly
2. Kink radius
3. Tensile strength of sheath blank material
4. "In use" simulation test - advancing and retracting the Brockenbrough needle in the sheath introducer
5. Tensile test results - all bonds and joints
6. Flexibility and maneuverability test

Additional biocompatibility testing was also provided in the submission.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 1998

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

Re: K970229
Arrow Transseptal Super Arrow-Flex®
Percutaneous Sheath Introducer Set
Regulatory Class: II (two)
Product Code: 74 DYB
Dated: January 30, 1998
Received: February 4, 1998

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 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, 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) 594-4648. 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section 11 - Indications

The Arrow Transseptal Super Arrow-Flex® Percutaneous Sheath Introducer set, is intended for use in the hospital catheterization laboratory for the percutaneous introduction of various cardiovascular devices into the left side of the heart through the interatrial septum.

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(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K970229