5/4/99

K990829

Special 510(k): Device Modification
Arrow-Trerotola™ Percutaneous Thrombolytic Device

ATTACHMENT 1 – 510(K) SUMMARY

Submitter

Arrow International, Inc.
2400 Bernville Road
Reading, PA 19605
610-378-0131

Contact Person:

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

Summary prepared: March 10, 1999

Device Name

Arrow-Trerotola™ Percutaneous Thrombolytic Device or "PTD" - Class II at 21 CFR 870.5150, Embolectomy catheter.

Legally marketed predicate device

Arrow-Trerotola™ Percutaneous Thrombolytic Device or "PTD".

Device description

The device is a 5 Fr. X 65cm sterile, single use rotatable catheter with a 9mm fragmentation basket.

Intended use of the device

The Arrow-Trerotola™ Percutaneous Thrombolytic Device (PTD) Catheter, in conjunction with the Arrow Rotator Drive Unit (PT-03000-R), permits mechanical declotting of synthetic dialysis grafts.

Technological characteristics

The design of the Arrow-Trerotola PTD™ consists of a 5 Fr. outer sheath with and inner cable connected to a self-expanding fragmentation basket. The device is attached to a hand-held, disposable rotator drive unit that spins at 3000-RPM. The catheter is placed into the thrombosed graft via an introducer sheath. Once placed inside the clotted graft, the basket is deployed to expand and conform to the graft wall. The rotator is then activated and the spinning basket is withdrawn through the graft to macerate the thrombus. The homogenized clot can then be aspirated from the graft via the introducer sheaths.

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

The performance test information in the submission includes:

1) Basket cap – basket wires tensile/torque test
2) Basket sleeve – basket wires tensile/torque test
3) Basket sleeve – torque cable tensile/torque test
4) Torque cable tensile/torque test
5) Torque cable drive hub tensile/torque test
6) Outer catheter sleeve mold tensile test
7) Outer catheter extrusion tensile/torque test
8) Extrusion tip tensile test
9) Basket/cable fatigue simulated use test
10) Cable torque transmission test
11) Cable/catheter friction tensile test
12) Basket speed in radius simulated use test
13) Basket abrasion simulated use test

The results of the laboratory tests demonstrated that the device modification is as 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 4 1999

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

Re: K990829
Trade Name: Arrow-Trerotola™ PTD Percutaneous Thrombolytic Device
Regulatory Class: II
Product Code: MCW
Dated: April 16, 1999
Received: April 20, 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 (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.

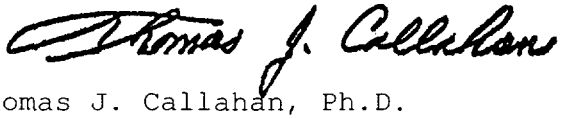
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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) 594-4586. 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" (21CFR 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory and Neurological Devices
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Enclosure

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SECTION 12 – INDICATIONS FOR USE STATEMENT

Device Name

Arrow-Trerotola™ Percutaneous Thrombolytic Device (PTD) Catheter.

Indications for Use

The Arrow-Trerotola™ Percutaneous Thrombolytic Device (PTD) Catheter, in conjunction with the Arrow Rotator Drive Unit (PT-03000-R), permits mechanical declotting of synthetic dialysis grafts.

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(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990829