



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20856

JUL 25 1997

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

Re: K970080  
Arrow-Trerotola™ Percutaneous Thrombolytic Device  
Regulatory Class: II (two)  
Product Code: MCW  
Dated: July 22, 1997  
Received: July 23, 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 (Pre-market 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 pre-market 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, Ph.D.  
Director  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

SECTION 2 - 510(k) SUMMARY

The device is substantially equivalent to the Angiodynamics Pro™ Infusion Catheter used in conjunction with a thrombolytic agent, such as Urokinase, in a pulse-spray thrombolytic procedure. K970080

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 acute clot in thrombosed dialysis grafts.

The device has comparable technological characteristics to the predicate device.

The nonclinical test results included in the submission are as follows:

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Animal Studies

1. Evaluation of venous injury caused by a percutaneous mechanical thrombolytic device - rabbit study.
2. Pulmonary emboli from pulse-spray and mechanical thrombolysis: Evaluation with an animal Dialysis Graft Model.
3. Preclinical in-vivo testing of a rotational mechanical thrombolytic device.

Bench Testing

1. Basket durability test
2. Mechanical tests
  - A. Destructive tensile and destructive torque testing for the following device joints, or bonds:
    - Torque cable
    - Stiffness rod-to-torque cable
    - Splined Luer hub-to-torque cable
    - Nitinol basket wires-to-metal cap and sleeve
    - Nitinol basket-to-torque cable
    - Plastic tip-to-metal cap
    - Hemostasis hub-to-sheath extension sleeve
    - Side arm-to-hemostasis hub
    - Luer hub-to-hemostasis hub side arm

Biocompatibility Testing

All components tested per ISO 10993.

Clinical evaluation results from IDE G950225 are included in the submission, and are summarized below.

A 122 patient randomized study comparing mechanical thrombolysis (PTD) to pulse-spray thrombolysis was recently completed at six institutions. The results of this clinical trial support claims for (1) equivalency in acute technical patency rates, (2) equivalency in acute major complication rates, and (3) reduced mean procedure time. In addition, the results support secondary claims of (1) equivalency in the rates of any complication (major or minor) and (2) equivalency in 3 month clinical patency rates.

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SECTION 10 - INDICATIONS

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

*Tau K. Ryan*

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(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Services  
510(k) number K970080