SECTION 2. 510(k) SUMMARY

510(k) Summary

Submitter:

Arrow Interntional, 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:	June 15, 1998

Device:

Trade Name:	Arrow Balloon Embolectomy Catheter
Common Name:	Embolectomy Catheter
Classification Name:	Catheter embolectomy, 74DXE, and 21 CFR 870.5150, Embolectomy catheter

Legally marketed device to which the device is substantially equivalent:

1. Arrow 5 Fr Balloon Wedge Pressure Catheter, AI-07123, a pre-amendment device. (Arrow Balloon Wedge Pressure Catheter)

2. Baxter 4 Fr Fogarty® Thru-Lumen Embolectomy Catheter, 12TLW804F, Premarket notification number: K892410. (Baxter Catheter)

Description of device:

The proposed device is identical to the legally marketed Arrow Single-Lumen 5F x 60 cm Balloon Wedge Pressure Catheter with regards to materials, construction, and manufacturing processes. Minor modifications have been made to the catheter tip and the latex balloon to enhance performance.

The functions and indications for use of the new device are substantially equivalent to those of the Baxter Fogarty® Thru-Lumen Embolectomy Catheter, K892410.

Intended use of the device:

This device is intended to be used only as (and only indicated as) an accessory to our Arrow-Trerotola PTD™ Percutaneous Thrombolytic Device. It is intended to be used on patients who are experiencing hemodialysis graft malfunction, due to thrombosis. This device is to be used to pull the arterial plug, located at the arterial anastamosis, into the arterial limb of the graft so it can be macerated by using the Arrow-Trerotola PTD™ Percutaneous Thrombolytic Device and removed.

Technological characteristics:

The device has the same technological characteristics as the predicates, with the only difference being the longer catheter tip and heavier wall latex balloon to enhance performance.

The performance tests included in the submission include:

1. Latex balloon tensile test
2. Biocompatibility tests
3. Catheter Integrity tests

No clinical testing was performed.

The results of the laboratory tests demonstrated that the device is safe, and as effective, if not more effective, as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 1998

Mr. Thomas D. Nickel
Arrow International, Inc.
2400 Bernville Road
Reading, PA 19605

Re: K982141
Arrow Balloon Embolectomy Catheter
Regulatory Class: II (two)
Product Code: DXE
Dated: June 15, 1998
Received: June 17, 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 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) 594-4648. 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/dsma/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 10. INDICATIONS

The Arrow Balloon Embolectomy Catheter is indicated for use as an accessory to the Arrow-Trerotola PTD™ Percutaneous Thrombolytic Device. It is intended to be used to remove the arterial plug from the arterial anastamosis of a thrombosed hemodialysis access graft.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K982141