K973465

APPENDIX VIII

510(k) SUMMARY FEB 19 1998

510(k) NUMBER:	PENDING
SUBMITTED BY:	Applied Medical Resources Corporation 26051 Merit Circle, #103 Laguna Hills, California 92653 (714) 582-6120 EXT. 326
CONTACT PERSON:	Mary Jo Stegwell
DATE OF PREPARATION:	September 10, 1997
NAME OF DEVICE:	Dual Lumen Graft Cleaning Catheter
CLASSIFICATION NAME:	Embolectomy Catheter
TRADE NAME:	Applied Medical *latis*™ Dual Lumen Graft Cleaning Catheter

SUMMARY STATEMENT:

The Applied Medical Dual Lumen Graft Cleaning Catheter is a single-use catheter intended for removal of thromboemboli from vascular grafts.

Mechanical safety and biocompatibility tests were performed to verify functional safety, structural integrity and material safety. All testing demonstrated that the Applied Medical Graft Cleaning Catheter is comparable to the predicate devices (K910372, K950586, K970762) and introduces no new safety and effectiveness issues when used as indicated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 1998

Ms. Mary Jo Stegwell
Vice President, Regulatory Affairs
Applied Medical Resources
26051 Merit Circle, #104
Laguana Hills, CA 92653

Re: K973465
Applied Medical *latis*™ Dual Lumen Graft Cleaning Catheter
Regulatory Class: II (Two)
Product Code: DXE
Dated: November 20, 1997
Received: November 21, 1997

Dear Ms. Stegwell:

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

510(k) Number (if known): K973465

Device Name: Applied Medical *latis*™ Dual Lumen Graft Cleaning Catheter

Indications For Use: The Applied Medical *latis*™ Dual Lumen Graft Cleaning Catheter is a disposable catheter intended for use in the removal of thrombus from vascular grafts and for occlusion and infusion of fluids into a graft.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K973465

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)