K972572

JAN 13 1998

Section 2

510(k) Summary

Single Lumen Embolectomy Catheter
American BioMed, Inc.
The Woodlands, Texas 77380

Section 2
510(k) Premarket Notification Summary

July 1997

Steven Rash
President and CEO
American BioMed, Inc
P. O. Box 8429
The Woodlands, Texas 77387-8429
(281) 367-3895
(281) 367-3212 Fax

CLASSIFICATION NAME:	Catheter, Embolectomy
COMMON/USUAL NAME:	Single Lumen Embolectomy Catheter
PROPRIETARY NAME:	Single Lumen Embolectomy Catheter
CLASSIFICATION:	21 CFR Part 870.5150 Catheter, Embolectomy
PERFORMANCE STANDARDS:	No Performance Standards for the Catheter, Embolectomy are effective as of this date.
PREDICATED DEVICE	Catheter Embolectomy K881455 and K905139, American BioMed, (CathLab Corp.) and Baxter Fogarty® Arterial Embolectomy Catheter.
DEVICE DESCRIPTION	Single Lumen Embolectomy catheter with three 100% silicone balloons. Catheter intended for use in removing arterial emboli. Sizes 2 to 7 French.
INDICATIONS	Removing arterial emboli.
TECHNOLOGICAL CHARACTERISTICS	This modification of K881455 and K905139, changes the number of balloons, two balloons are located at the distal end for embolus removal purpose, the third balloon is located at the proximal end as a safety balloon to prevent over injection of fluid.
SUBSTANTIAL EQUIVALENCE	The Single Lumen Embolectomy Catheter is equivalent to K881455, K905139, and Baxter

Fogarty Arterial Embolectomy Catheter, same intended use, with change in number of balloons.

Statement of Similarities and Differences

Parameter	American BioMed Single Lumen Embolectomy Catheter	American BioMed Single Lumen Catheter K881455 & K905139	Baxter Fogarty Arterial Embolectomy Catheter K No. Not Found in FDA 510(k) Data Base
Body Material	Silicone Compound	Silicone Compound	Polyvinylchloride
Balloon Material	Silicone Compound	Silicone Compound	Latex
Balloon to Body Bonding	No. All Silicone. Formed through dipping process	No. All Silicone. Formed through dipping process	Yes
Number of Balloons	Three. Two at distal end and one at proximal end.	One. At distal end.	One. At distal end.
Catheter French Sizes	2, 3, 4, 5, 6, and 7	2, 3, 4, 5, 6, and 7	2, 3, 4, 5, 6, and 7
Catheter Length	40, 60, 80, 100 cm.	40, 60, 80, 100 cm.	40, 60, 80, 100 cm.
Inflated Balloon Diameter	2 Fr. - 4 mm 3 Fr. - 5 mm 4 Fr. - 9 mm 5 Fr. - 11 mm 6 Fr. - 13 mm 7 Fr. - 14 mm	2 Fr. - 4 mm 3 Fr. - 5 mm 4 Fr. - 9 mm 5 Fr. - 11 mm 6 Fr. - 13 mm 7 Fr. - 14 mm	2 Fr. - 4 mm 3 Fr. - 5 mm 4 Fr. - 9 mm 5 Fr. - 11 mm 6 Fr. - 13 mm 7 Fr. - 14 mm
Maximum Liquid Volume	2 Fr. - 0.05 ml 3 Fr. - 0.10 ml 4 Fr. - 0.50 ml 5 Fr. - 0.75 ml 6 Fr. - 1.25 ml 7 Fr. - 2.00 ml	2 Fr. - 0.05 ml 3 Fr. - 0.10 ml 4 Fr. - 0.50 ml 5 Fr. - 0.75 ml 6 Fr. - 1.25 ml 7 Fr. - 2.00 ml	2 Fr. - N/A 3 Fr. - 0.20 ml 4 Fr. - 0.75 ml 5 Fr. - 1.50 ml 6 Fr. - 2.00 ml 7 Fr. - 2.50 ml
Intended Use	Removing arterial emboli	Removing arterial emboli	Removing arterial emboli

CONCLUSIONS

The conclusion drawn from the above is that the modified American BioMed Single lumen Embolectomy Catheters are equivalent in safety and efficacy to their predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 1998

American Biomed, Inc
c/o J. Harvey Knauss
Delphi Consulting Group
11874 South Evelyn Circle
Houston, Texas 77071

Re: K972572
Single Lumen Embolectomy Catheter
Regulatory Class: II (two)
Product Code: DXE
Dated: October 17, 1997
Received: October 21, 1997

Dear Mr. Knauss:

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)

Device Name: Single Lumen Embolectomy Catheter

Indications for use: Removing arterial emboli.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K970572