K993057

OCT 5 1999

Attachment 4

510(k) Summary

SAFETY AND EFFECTIVENESS SUMMARY

This information of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitted by Name/Address:	Chester McCoy Regulatory Affairs Engineer Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 253-1600 ext. 404 (801) 253-1684 fax
Contact Person:	Same as above
Date Summary Prepared:	September 9, 1999
Device Name:	MBA Hemostasis Valves
Common Name:	Hemostasis Valves
Trade Name:	MBA
Classification (if known):	Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting (74DTL) Class II
Predicate Device:	Passage™ Hemostasis Valve (k925419)

Device Description:	The MBA™ is a Dual Seal Hemostasis Valve with an integral introducer
Performance Standards:	Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.
Intended Use:	The MBA Hemostasis Valves are designed for use during percutaneous transluminal angioplasty (PTA) and other intravascular therapeutic procedures that utilize a guiding catheter.
Device Use:	During angioplasty and other interventional procedures, the patient's vasculature is accessed through a peripheral artery. To control bleed-back from the artery, a hemostasis valve is attached to the external female luer of a guiding catheter. This device is typically 'y' shaped with a female luer and a manual hemostasis valve. The female port is attached to a manifold system to allow for contrast injections and pressure monitoring, while the hemostasis valve allows controlled direct arterial access when using a guide wire and/or interventional therapy devices.
Biocompatibility:	All materials used in the MBA Hemostasis Valves are biocompatible.
Summary of Substantial Equivalence:	The Merit MBA Hemostasis Valves are substantially equivalent to the previously cleared Merit Passage Hemostasis Valves.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 5 1999

Mr. Chester McCoy
Regulatory Affairs Engineer
Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, UT 84095

Re: K993057
Trade Name: MBA™ Hemostasis Valves
Regulatory Class: II
Product Code: DTL
Dated: September 9, 1999
Received: September 13, 1999

Dear Mr. McCoy:

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

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number (if Known)

Device Name MBA ™ Hemostasis Valves

Indications for Use The MBA Hemostasis Valves are designed for use during percutaneous transluminal angioplasty (PTA) and other intravascular therapeutic procedures that utilize a guiding catheter.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Christopher M. Hu for Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K993057

Prescription Use X OR Over-The-Counter Use_____