MERIT MEDICAL

K990975

MAR 15 2000

510(k) SUMMARY

This summary was prepared on March 19, 1999

Submitter's name: Chester McCoy, RA
Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, Utah 84095
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Contact Person: Same as above

Name of device: IN-LINE Hemostasis Valve (Passage™)

Common name: Hemostasis Valve

Classification name: Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting (74DTL)

Predicate device: Merit Y-adaptor with hemostasis valve

MERIT MEDICAL
SYSTEMS, INC.
1600 WEST
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UTAH 84095
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PRODUCT DESCRIPTION

A hemostasis valve is a device which is used to control the amount of blood loss or fluid flow while permitting vasculature access. An "in-line" hemostasis valve is a device used to control fluid which is geometrically configured in a single straight path. The inner lumen does not have additional or intersecting fluid paths.

INTENDED USE

The Merit IN-LINE Hemostasis Valve is recommended for minimizing back bleeding when a catheter, guide wire or similar device is placed in the vascular system as well as maintaining a fluid-tight seal around interventional devices, catheters, and guide wires.

SUBSTANTIAL EQUIVALENCE STATEMENT

The IN-LINE Hemostasis Valve is manufactured from plastics that have a history of safe blood contact use. Products have been tested to substantiate Merit's claim that the hemostasis provides a leak-proof seal around angioplasty catheters and guide wires. The IN-LINE Hemostasis Valve's intended use is similar to the predicate device's intended use.

Therefore, Merit Medical Systems, Inc. believes this product is substantially equivalent to the predicate device and that its introduction into interstate commerce will not raise new questions of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2000

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

Re: K990975
Merit IN-LINE™ Hemostasis Valve
Regulatory Class: II (two)
Product Code: DYB
Dated: December 15, 1999
Received: December 16, 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) 594-4648. 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,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if Known)	K990975
Device Name	INspector™ Hemostasis Valve
Indications for Use	The IN-LINE Hemostasis Valve is recommended for minimizing back bleeding when a catheter, guide wire or similar device is placed in the vascular system as well as maintaining a fluid-tight seal around interventional devices, catheters, and guide wires.

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 K990975

Prescription Use X OR Over-The-Counter Use_____