K072556

SECTION 5: 510(k) SUMMARY

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

NOV 2 0 2007

CONTACT: Shirley Hyink

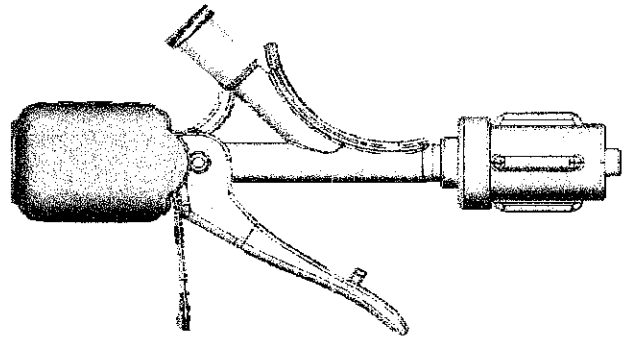
DATE PREPARED: September 7, 2007

TRADE OR PROPRIETARY NAME: Hemostasis Valve

CLASSIFICATION NAME: Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting
21CFR 870.4290

PREDICATE DEVICE: Merit Passage® Hemostasis Valve (K925419)

DEVICE DESCRIPTION: The Hemostasis Valve is a valve consisting of a clear polycarbonate body, silicone valve, polyacetal actuation lever, and polycarbonate and EPDM o-ring rotating male Luer lock connector and female Luer lock.



INTENDED USE: The Hemostasis Valve is intended to maintain a fluid-tight seal around interventional and diagnostic devices during use.

TECHNOLOGICAL CHARACTERISTICS: The Hemostasis Valve and the predicate device Passage are similar in design and technology. All of the component materials found in the Hemostasis Valve have been used in legally marketed Merit devices and were found safe for their intended use.

The prior use of component materials of the Hemostasis Valve in legally marketed devices, a similar indication for use, the performance data provided, and the biocompatibility statement support the safety and effectiveness of this hemostasis valve for the indicated use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2007

Merit Medical Systems, Inc.
c/o Ms. Shirley Hyink
Manager, Regulatory Affairs
1600 West Merit Parkway
South Jordan, UT 84095

Re: K072556
Hemostasis Valve
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, or Fitting
Regulatory Class: Class II
Product Code: DTL
Dated: September 7, 2007
Received: September 10, 2007

Dear Ms. Hyink:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Lechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE

510(k) Number (if known): K072556

Device Name: Hemostasis Valve

Indications for Use:

The Hemostasis Valve is indicated to maintain a fluid-tight seal around interventional and diagnostic devices during use.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072556