DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2003

Merit Medical Systems, Inc.
c/o Mr. John W. Nicholson
Senior Regulatory Affairs Specialist
1600 West Merit Pkwy
South Jordan, UT 84095

Re: K031922
Captiva™ Blood Containment Device
Regulation Number: 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: September 11, 2003
Received: September 12, 2003

Dear Mr. Nicholson:

This letter corrects our substantially equivalent letter of October 1, 2003 regarding the address change.

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 (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.

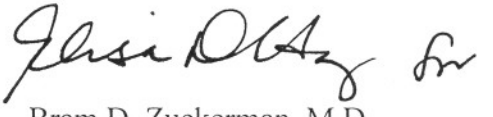
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



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

K031922

OCT - 1 2003

510(k) Summary of Safety and Effectiveness

Submitter's Information:

Merit Medical Systems, Inc.
1600 W. Merit Parkway
South Jordan, UT 84095
Phone- 801-253-1600
FAX – 801-253-1684
Contact: John W. Nicholson
Alternate Contact: Jerrie Hendrickson
Preparation Date: June 19, 2003

Device Information

Trade Name: Captiva™ Blood Containment Device
Common Name: Blood Containment Device
Classification Name: Catheter Introducer
Classification Number: 870.1340 - Class II

Predicate Device: Novoste™ PulsePlus Blood Containment Device

Product Description: The Captiva™ Blood Containment Device is designed to contain the flow of a patient's blood during vascular access procedures, thereby helping to reduce the healthcare professionals' exposure to bloodborne pathogens while controlling patient blood loss. It also provides for vascular access by maximum 0.038 inch guidewires.

Intended Use: The Captiva Blood Containment Device is intended for blood containment during vascular access procedures. Upon entering the vessel, the Captiva Blood Containment Device provides visualization of flashback and containment of blood within a sealed chamber. It also allows placement of a guidewire through the device for subsequent catheterization.

Technological Characteristics: Both the predicate and applicant devices achieve equivalent clinical functions by utilizing medical grade, biocompatible materials for blood containment during vascular access procedures. Both devices also help to reduce clinician exposure to patient blood while still allowing for guidewire access through the device. Both devices provide a visualization chamber to identify correct vessel access. The devices' sub-components are similar in shape, size, materials used and function. The materials of construction and design, though not identical, are sufficiently similar to provide for equivalent pre-clinical performance data. No new safety and effectiveness issues arise as a result of the proposed device modifications.

Non-Clinical Testing: Merit has performed a series of pre-clinical tests to support a substantially equivalent determination and/or to demonstrate the device's safety and efficacy when used as intended.

The performance data indicate that the applicant and the predicate devices have substantially equivalent values. They also indicate that the modified design of the applicant device is sufficiently robust for its intended use. There is no indication that the proposed modifications have any deleterious effects on applicant device performance and no new safety and efficacy questions arise when the applicant device is used as intended.

Conclusion: The Captiva™ Blood Containment Device has met all pre-determined acceptance criteria. Based upon FDA's substantial equivalence criteria, the Captiva™ Blood Containment Device has been demonstrated to be substantially equivalent to the predicate Novoste™ PulsePlus Blood Containment Device.

Indications for Use Statement*

510(k) Number (if known): K031922

Device Name: Captiva™ Blood Containment Device

Indications for Use: The Captiva Blood Containment Device is intended for blood containment during vascular access procedures. Upon entering the vessel, the Captiva Blood Containment Device provides visualization of flashback and containment of blood within a sealed chamber. It also allows placement of a guidewire through the device for subsequent catheterization.

Signature of 510(k) Submitter John W. Nicholson

Printed Name of Submitter: John W. Nicholson,

Senior Regulatory Affairs Specialist

Date: Sept. 10, 2003

*Suggested language and format to meet the requirements of 513(i) of FD&C Act, as amended, and sections 807.92 and 801.4 of 21CFR.

Concurrence of Office of Device Evaluation

510(k) Number K031922

Division Sign-off

Office of Device Evaluation

Prescription Use X OR Over-the-Counter Use _____