K082613

DEC 30 2008

Section 5

510(k) Summary

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan, UT 84095
	Telephone Number:	(801) 208-4196
	Fax Number:	(801) 253-6932
	Contact Person:	Michaela Rivkowich
	Date of Preparation:	September 5, 2008
	Registration Number:	1721504
Subject Device	Trade Name:	To be assigned
	Common/Usual Name:	Merit Microcatheters
	Classification Name:	Continuous Flush Catheter
Predicate Device	Trade Name:	Renegade™ Fiber Braided Microcatheter with Hydro Pass™ Hydrophilic Coating
	Classification Name:	Continuous Flush Catheter
	Premarket Notification:	K973645
	Manufacturer:	Boston Scientific Corporation
Classification	Class II 21 CFR § 870.1210, 74 KRA Division of Cardiovascular, Respiratory and Neurological Devices	
Intended Use	The Merit Microcatheter is intended for general intravascular use, including peripheral and coronary vasculature. Once the subselective region has been accessed, the microcatheter can be used for the controlled and selective infusion of diagnostic, embolic or therapeutic materials into vessels.	

Device Description	The Merit Microcatheter is available in 2.8/2.8 Fr and 2.8/2.4 Fr sizes with lengths of 110, 130 and 150 cm. The outer surface of the distal segment of the catheter shaft is coated with a hydrophilic coating designed to facilitate the introduction of the catheter into the vessels. The Microcatheter has a radiopaque marker at the distal tip to facilitate fluoroscopic visualization.
Safety & Performance Tests	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, a battery of tests was performed according to protocols based on the requirements of the following documents, and were shown to meet the acceptance criteria that were determined to be applicable to the safety and efficacy of the device: • ISO 10555-1: 1995, *Sterile, single-use intravascular catheters, Part 1. General requirements.* • ISO 10555-2: 1996, *Sterile, single-use intravascular catheters, Part 2. Angiographic catheters* • ISO 594-2:1998, *Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings* • ISO 11135: 1994, *Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization* • ISO 10993-1: 2003, *Biological Evaluation of medical Devices Part 1: Evaluation and Testing,* and the FDA Modified ISO 10993 Test Profile
Summary of Substantial Equivalence	Based on the indications for use, design, and safety and performance testing, the subject Merit Microcatheter meets the minimum requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Renegade™ Fiber Braided Microcatheter with Hydro Pass™ Hydrophilic Coating, manufactured by Boston Scientific Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Merit Medical Systems, Inc.
c/o Mr. Glenn Norton
Director of Regulatory Affairs
1600 West Merit Parkway
South Jordan, UT 84095

DEC 3 0 2008

Re: K082613
Trade/Device Name: Merit Microcatheter
Common Name: catheter, continuous flush
Regulation Number: 21 CFR 870.1210
Regulatory Class: II
Product Code: KRA
Dated: December 19, 2008
Received: December 22, 2008

Dear Mr. Norton:

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 Biometrics' (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,

M. J. Hillebrenner

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

Enclosure

510(k) Number (if known): K082613

Device Name: Merit Microcatheters

Indications for Use:

The Merit Microcatheter is intended for general intravascular use, including peripheral and coronary vasculature. Once the subselective region has been accessed, the microcatheter can be used for the controlled and selective infusion of diagnostic, embolic or therapeutic materials into vessels. The catheter should not be used in the cerebral vessels.

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

M. J. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082613