K093004

Section 5

510(k) Summary FEB 12 2010

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 25, 2009
	Registration Number:	1721504
Subject Device	Trade Name:	Impress® Angiographic Catheter with Hydrophilic Coating
	Common/Usual Name:	Angiographic Catheter
	Classification Name:	Diagnostic Intravascular Catheter
Predicate Device	Trade Name:	Impress® Angiographic Catheter
	Classification Name:	Diagnostic Intravascular Catheter
	Premarket Notification:	K053171
	Manufacturer:	Merit Medical Systems, Inc.
Predicate Device	Trade Name:	Radifocus® Glidecath™
	Classification Name:	Diagnostic Intravascular Catheter
	Premarket Notification:	K915414
	Manufacturer:	Terumo Corporation
Classification	Class II 21 CFR § 870.1200, 74 DQO Division of Cardiovascular Devices	
Intended Use	Angiography catheters are designed to be used for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures. Angiographic catheters with marker bands may also be used for anatomical measurements.	

Device Description	The Impress® Angiographic Catheters with hydrophilic coating are single lumen catheters offered in 4F and 5F sizes and 40cm to 125cm. The outer surface of the distal segment of the catheter shaft is coated with a hydrophilic coating.
Technological Characteristics	Technological characteristics of the subject Impress catheter with hydrophilic coating are substantially equivalent to those of the predicate devices, the Impress Angiographic Catheter (K053171) and the Radifocus Glidecath Angiographic Catheter (K915414).
Safety & Performance Tests	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, testing was performed demonstrating that the subject device met the acceptance criteria determined to demonstrate the safety and efficacy of the device.
Summary of Substantial Equivalence	Based on the indications for use, design, safety and performance testing, the subject Impress® Angiographic Catheter with hydrophilic coating is substantially equivalent to the predicate devices, the Impress® Angiographic Catheter, manufactured by Merit Medical Systems, Inc., and the Radifocus Glidecath Angiographic Catheter, manufactured by Terumo Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Merit Medical Systems, Inc.
c/o Ms. Michaela Rivkowich
Regulatory Affairs Specialist III
1600 West Merit Parkway
South Jordan, UT 84095

FEB 12 2010

Re: K093004
Trade/Device Name: Impress® Angiographic Catheter with Hydrophilic Coating
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II (two)
Product Code: DQO
Dated: January 28, 2010
Received: January 29, 2010

Dear Ms. Rivkowich:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Donna R. Richmond

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): K093004

Device Name: Impress® Angiographic Catheter with Hydrophilic Coating

Indications for Use:

Angiography catheters are designed to be used for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures. Angiographic catheters with marker bands may also be used for anatomical measurements.

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)

Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093004