SEP 21 2012

Section 5

510(k) Summary

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 316-4956 (801) 253-6982 David Thomas July 11, 2012 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name:	Ostial Pro Stent Positioning System Stent Positioning System Catheter Guidewire
Predicate Device	Trade Name: Common/Usual Name: Classification Name: Premarket Notification: Manufacturer:	Ostial Pro Stent Positioning System Stent Positioning System Catheter Guidewire K062192 Merit Medical Systems, Inc.
Classification	Class II 21 CFR § 870.1330 Cardiovascular	
Intended Use	The Ostial Pro Stent Positioning System is intended for use in aorta-ostial procedures to introduce and position stents and other interventional devices within the coronary and peripheral vasculature. In addition, the Ostial Pro Stent Positioning System is intended to facilitate the alignment of interventional devices and function as an alignment tool.	

Device Description	The Ostial Pro Stent Positioning System is a medical grade, disposable guidewire system. The Ostial Pro Stent Positioning System will be used by interventional cardiologists and interventional radiologists to ensure precise stent implantation in aorta-ostial procedures. The product will be used in coronary and renal stenting procedures. This product is provided sterile and intended for single use. This finished product will be compatible with 6, 7 and 8 French catheters.
Technological Characteristics	The technological characteristics of the subject Ostial Pro Stent Position System are substantially equivalent to those of the predicate device, the Ostial Pro Stent Positioning System, 510(k) K062192.

Safety & Performance Tests	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject Ostial Pro Stent Positioning System was conducted based on the risk analysis and based on the requirements of the following FDA guidance document and international standards: • AAMI/ANSI/ISO 11135-1: 2007, *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* • AAMI/ANSI/ISO 11607-1: 2006, Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems • ISO 2233:2000, *Packaging – complete, filled transport packages and unit loads – conditioning and testing* • ASTM D4169-09, *Standard practice for performance testing of shipping containers and systems* • *AAMI/ANSI/ISO 10993-7: 2008 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals* • *ASTM F1980:2007* Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. • Coronary and Cerebrovascular Guidewire Guidance – Jan 1995 • Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems – April 2010. The following is a list of all significant testing that was successfully completed:

Safety & Performance Tests cont.	<u>Design Verification</u> Dimensions Torque Strength Torque-Ability Feet Deflection Force Test Body Af (Austenite Finish Temperature) Test Wire Af Test Coating Adherence/Integrity Catheter Compatibility Radio-opacity Feet Force Deflection/Compression Test Fatigue Loading of Feet Linear Tensile Strength Angular Tensile Strength
Safety & Performance Tests cont.	The results of the testing demonstrated that the subject Ostial Pro Stent Positioning System met the pre-determined acceptance criteria applicable to the safety and efficacy of the device.
Summary of Substantial Equivalence	Based on the indications for use, design, and safety and performance testing, the subject Ostial Pre Stent Positioning System meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Ostial Pro Stent Positioning System, manufactured by Ostial Solutions LLC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 21 2012

Merit Medial Systems, Inc.
c/o David Thomas
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K122089
Trade/Device Name: Ostial Pro Stent Positioning System
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guidewire
Regulatory Class: Class II
Product Code: DQX
Dated: August 23, 2012
Received: August 24, 2012

Dear Mr. Thomas:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for 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): K122089

Device Name: Ostial Pro Stent Positioning System

Indications for Use:
The Ostial Pro Stent Positioning System is intended for use in aorta-ostial procedures to introduce and position stents and other interventional devices within the coronary and peripheral vasculature. In addition, the Ostial Pro Stent Positioning System is intended to facilitate the alignment of interventional devices and function as an alignment tool.

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 K122089