DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 3, 2016

Merit Medical Ireland Ltd.
C/O Ms. Stephanie Erskine
1600 West Merit Parkway
South Jordan, UT 84095

Re: K110643
Trade/Device Name: Merit Marquis Flow Switch
Regulation Number: 21 CFR 870.4290
Regulation Name: Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass
Regulatory Class: Class II
Product Code: DTL
Dated: April 20, 2011
Received: April 22, 2011

Dear Ms. Erskine:

This letter corrects our substantially equivalent letter of July 1, 2011.

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Eric E. Richardson -S

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

Enclosure

Section 4

Indications for Use Statement

510(k) Number (if known): K110643

Device Name: Merit Marquis® Flow Switch

Indications for Use:

The Flow Switch is an angiographic accessory intended for use as an on-off device for angiography and other high pressure applications.

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)

F. Chen for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110643

Section 5

510(k) Summary

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Contact Person: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 208-4349 (801) 253-6967 Stephanie Erskine 1721504
	Correspondent Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Ireland Ltd. Parkmore Business Park, Galway, Ireland (353) 91 703 761 (353) 91 771 888 Mark Mullaney 21-Apr-2011 9616662
Subject Device	Trade Name: Common/Usual Name: Classification Name:	Merit Marquis® Flow Switch High pressure angiographic flow control switch / stopcock Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	FLOSWITCH(R) HP Catheter, intravascular, diagnostic K913871 BOSTON SCIENTIFIC CORP.
Classification	Class II FDA Product Code: DTL 21 CFR § 870.4290 Division of Cardiovascular Devices	
Intended Use	The Flow Switch is an angiographic accessory intended for use as an on-off device for angiography and other high pressure applications.	

Device Description	The Flow Switch is a device used to connect in line to liquid flow. This uses a Female Luer lock (inlet) and Male Luer lock (outlet) connection. Shut off is by means of a non-slip sliding handle that can be operated one-handed and gives an audible click into the OFF position. Flow directions are indicated by arrows on the handle.
Technological Characteristics	Technological characteristics of the subject Merit Marquis® Flow Switch are substantially equivalent to those of the predicate, the currently marketed BOSTON SCIENTIFIC CORP. FLOSWITCH(R) HP [K913871].
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 performed on the Merit Marquis® Flow Switch were designed to demonstrate that the device meets critical design specifications as well as clinical performance attributes for its intended use. Where appropriate, the tests were based on the requirements of the following documents: • ISO 11070: 1998, Sterile Single-Use Intravascular Catheter Introducers. • ISO 594-1:1996, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements* • ISO 594-2:1998, *Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings* • ASTM F 2096-04; Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test) • ASTM F 1929-98 (Reapproved 2004); Standard Test Method for Detecting Seal Leaks in porous Medical Packaging by Dye Penetration • ASTM F 88-07; Standard Test Method for Seal Strength of Flexible Barrier Materials. • ASTM D4169 – 09 Standard Practice for Performance Testing of Shipping Containers and Systems1 • ISO 11135:2007 – *Sterilization of health care products – Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* • ISO 10993-1: 2009, *Biological Evaluation of medical Devices Part 1: Evaluation and Testing within a risk management process,* and the FDA Modified ISO 10993 Test Profile

The Merit Marquis® Flow Switch was compared to the predicate device for various performance attributes that demonstrate the safety or efficacy of the device. The following is a list of all significant testing that was successfully completed:

- Surface inspection
- Male and Female Luer conical fittings with a 6% (Luer)
- Pressure in OFF position
- Pressure in open/ON position
- Slider Handle motion test
- Slider force test
- Flow Test

Biocompatibility testing included:

- L929 MEM Elution: MEM extraction
- Kligman Maximization: Saline and cottonseed oil extractions
- Intracutaneous Injection: Saline and cottonseed oil extractions
- Systemic Injection: Saline and cottonseed oil extractions
- Material Medicated Rabbit Pyrogen Test: Saline extraction
- Hemocompatibility – In-Vitro Hemocompatibility – Indirect
- Hemocompatibility – Hemolysis – Indirect
- Hemocompatibility – Prothrombin Time Assay (PT) – Indirect
- Hemocompatibility – Unactivated Partial Thromboplastin Time Assay (UPTT) Indirect
- Heavy Metals Content: USP Physicochemical Tests for Plastics USP <661>

Packaging performance before and after exposure to accelerated aging and simulated shipping and handling conditions:

- Bubble emission
- Dye penetration
- Seal peel tensile strength
- Burst strength
- Visual inspection

Summary of Substantial Equivalence

Based on the indications for use, design, safety, and performance testing, the subject Merit Marquis® Flow Switch meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the currently marketed FLOSWITCH(R) HP manufactured by currently marketed BOSTON SCIENTIFIC CORP.