



January 16, 2019

Merit Medical Singapore Pte. Ltd.
Xing Seow
Regulatory Affairs Specialist
198 Yishun Avenue 7
Singapore, 768926 Sg

Re: K182538
Trade/Device Name: Merit RadialFlo Arterial Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: December 12, 2018
Received: December 17, 2018

Dear Xing Seow:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen C. Browning -S5

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K182538

Device Name

Merit RadialFlo Arterial Catheter

Indications for Use (Describe)

The Merit RadialFlo Arterial Catheter is a device that is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood and monitor blood pressure. The Merit RadialFlo Arterial Catheter may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5.0 510(k) Summary

General Provisions	Submitter Name:	Merit Medical Singapore Pte. Ltd.
	Address:	198 Yishun Avenue 7, Singapore 768926
	Telephone Number:	(65) 6750-9188
	Fax Number:	(65) 6754-3961
	Contact Person:	Ms. Xing Ting Seow
	Date Prepared:	September 10, 2018
	Establishment Registration : Number	8020616
Subject Device	Trade Name:	Merit RadialFlo™ Arterial Catheter
	Common/Usual Name:	Arterial Catheter
	Classification Name:	Catheter, Intravascular, Therapeutic, short-term less than 30 days
Predicate Device	Trade Name:	BD Angiocath™ IV Catheter
	Common/Usual Name:	Peripheral Intravascular or IV Catheter
	Classification Name:	Catheter, Intravascular, Therapeutic, short-term less than 30 days
	Premarket Notification:	K151698
	Manufacturer:	Becton Dickinson Infusion Therapy System Inc.
Reference Device	Trade Name:	Merit Secalon T™ Catheter (previously named as Viggo Secalon T Catheter)
	Common/Usual Name:	Intravascular Catheter
	Classification Name:	Catheter, intravascular, therapeutic, short-term less than 30 days
	Premarket Notification:	K850460
	Manufacturer:	Merit Medical Singapore Pte. Ltd. (previously manufactured by Viggo Products Ohmeda)
Classification	Regulatory Class:	II
	Product Code:	FOZ
	21 CFR §:	880.5200
	Review Panel:	General Hospital

Intended Use	The Merit RadialFlo Arterial Catheter is a device that is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood and monitor blood pressure. The Merit RadialFlo Arterial Catheter may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure. The Indications for Use statement for the Merit RadialFlo Arterial Catheter device is same as the predicate device (K151698) except that the predicate device has additional use to administer fluids intravenously. Subject device has one less product claim and product does not have therapeutic effect. The difference does not affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices follow 21 CFR 880.5200 to sample blood and monitor blood pressure.			
Device Description	The Merit RadialFlo Arterial Catheter is an intravascular catheter designed to access the vasculature to sample blood and monitor blood pressure. The device is equipped with a Flowswitch to limit blood spill or control flow as needed. The needle includes a unique notch to provide instant blood return upon vessel entry. The radiopaque catheter provides visibility under X-ray and fluoroscopy. The arterial catheter is intended to be in contact with the circulating blood for a prolonged (24 hours to 30 days) duration. The steel needle is in contact with circulating blood for a limited (<24 hours) duration and the flow control plug has indirect blood path contact. All the materials used in Merit RadialFlo Arterial Catheter are biocompatible.			
Comparison to Predicate Device	The proposed Merit RadialFlo Arterial Catheter incorporates similar intended use, design and principle of operation as the predicate devices. Any differences in materials used or specification are supported by the subject device's compliance with FDA recognized standards ISO 10555-1 and ISO 10555-5. The subject device is substantially equivalent to the predicate device (K151698). The technology and design of the Flowswitch is the same as reference device. The material used on the subject device is same as the reference device (K850460) except the Flowswitch button is made using polyphenylene oxide but this has no body contact. There is also an additional component which is the flow control plug that is made of polypropylene with filter membrane to limit blood spill. The flow control plug has indirect blood contact.			
	Attribute	Subject Device – Merit RadialFlo Arterial Catheter	Predicate Device – BD Angiocath ^T _M IV Catheter (K151698)	Reference Device – Merit Secalon T Catheter (K850460)

	Design		A conventional over-the-needle intravascular catheter with radiopaque Polytetrafluoroethylene (PTFE) tubing. The needle introducer punctures the skin and allow penetration of the intravascular catheter to the blood vessel. The radiopaque catheter provides visibility under X-ray and fluoroscopy. The catheter is designed with a Floswitch hub with luer connection to control flow of fluid or blood. The needle cannula includes a unique notch to provide instant blood return for recognition of correct blood entry.	A conventional over-the-needle intravascular catheter with radiopaque fluorinated ethylene propylene (FEP) tubing. The needle introducer punctures the skin and allow penetration of the intravascular catheter to the blood vessel. The catheter provides visibility under X-ray and fluoroscopy. The catheter is designed with a conventional luer hub. A flash chamber for blood flash back for recognition of correct blood entry.	A conventional over-the-needle intravascular catheter with radiopaque Polytetrafluoroethylene (PTFE) tubing. The needle introducer punctures the skin and allow penetration of the intravascular catheter to the blood vessel. The catheter provides visibility under X-ray and fluoroscopy. The hub is designed with a Floswitch hub with luer connection to control flow of fluid or blood.
	Material				
	Arterial Catheter	Catheter Tube	Polytetrafluoroethylene (PTFE)	Fluorinated Ethylene Propylene	Polytetrafluoroethylene (PTFE) with

		with Barium Sulphate	(FEP) with radiopaque filler	Barium Sulphate
	Catheter Bush	Polycarbonate		Polycarbonate
	Floswitch Housing / Catheter Hub	Polypropylene, (colorant: pink)	Polypropylene (colorant: pink)	Polypropylene
	Floswitch Button	Polyphenylene Oxide		Acrylonitrile Butadiene Styrene
	Steel Ball	Stainless steel		Stainless steel
	Silicon Valve	Silicon rubber		Silicon rubber
	Guide Bush	Polycarbonate		Polycarbonate
Needle Introducer	Steel Needle	Stainless steel	Stainless steel	Stainless steel
	Needle Grip / hub	Polypropylene	Propionate	Polypropylene
Flow Control Plug / Vent Plug		Polypropylene, Acrylic copolymer membrane on nonwoven nylon	Polyethylene	NA
Protection Tube		Low Density Polyethylene	Polypropylene	Low Density Polyethylene
Lubricant		Polydimethylsiloxane	Polydimethylsiloxane	Polydimethylsiloxane
Principle of Operation		Over-Needle Technique	Over-Needle Technique	Over-Needle Technique
Catheter Diameter		20G	14G, 16G, 18G, 20G, 22G, 24G	14G, 16G, 18G
Catheter Length		45mm	19mm, 25mm, 30mm, 48mm, 83mm, 133mm	90mm, 130mm, 160mm
Indications for Use		The Merit RadialFlo Arterial Catheter is a device that	An intravascular catheter is a device	The Secalon-T Central Venous Catheter is

		is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood and monitor blood pressure. The Merit RadialFlo Arterial Catheter may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.	that is inserted into the patient's vascular system for short term use (less than 30days) to sample blood, monitor blood pressure, or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.	intended to access to the human circulatory system. This access allows large volume infusion of liquids, blood sampling and infusion of drugs. The Floswitch control the flow of liquids.
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FDA guidance and recognized consensus standards have been established for Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days under FDA Product Code FOZ and 21 CFR 880.5200. A battery of tests was performed based on the requirements of the below recognized consensus standards and guidance, as well as biocompatibility, sterilization, and labeling standards and guidance. Conformity to these standards demonstrates that the subject Merit RadialFlo Arterial Catheter met the standards' established acceptance criteria applicable to the safety and effectiveness of the device.

Safety & Performance Data

- ISO 10555-1: 2013, *Intravascular Catheters -- Sterile and Single-Use Intravascular Catheters -- Part 1: General Requirements*
- ISO 10555-5: 2013, *Intravascular Catheters -- Sterile and Single-Use Catheters -- Part 5: Over-Needle Peripheral Catheters*

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- ISO 80369-7:2016, Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic applications
 - ISO 9626: 2016, Stainless steel needle tubing for the manufacture of medical devices – Requirement and test methods
 - IEC 62366-1:2015, *Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]*
 - ISO 2233:2000, *Packaging – Complete, filled transport packages and unit loads – Conditioning for testing*
 - ISO 11607-1:2006, *Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems [Including: Amendment 1 (2014)]*
 - ISO 11607-2: 2006, *Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes [Including: Amendment 1 (2014)]*
 - ASTM D4169-16: 2016, *Standard Practice for Performance Testing of Shipping Containers and Systems*
 - ASTM F1980-16: 2016, *Standard Guide for Accelerated Aging of Sterile Barrier System for Medical Device*
 - ISO 10993-1:2009 / Cor 1:2010, *Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process [Including: Technical Corrigendum 1 (2010)]*
 - ISO 10993-4: 2017, *Biological evaluation of medical devices – Part 4: Selection of test for interactions with blood.*
 - ISO 10993-5:2009, *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
 - ISO 10993-10:2010, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
 - ISO 10993-11:2017, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
 - ISO 11135:2014, *Sterilization of Health Care Products – Ethylene Oxide – Requirements for The Development, Validation, and Routine Control of A Sterilization Process for Medical Devices*
 - ISO 10993-7:2008/Cor 1: 2009, *Biological Evaluation Of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals [Including: Technical Corrigendum 1 (2009)]*
 - AAMI TIR 28:2009, *Product Adoption and Process Equivalency for Ethylene Oxide Sterilization*
 - AAMI/ANSI ST72:2011/(R)2016, *Bacterial Endotoxins – Test methods, routine monitoring, and alternatives to batch testing*
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- United States Pharmacopeia 41, National Formulary 36, <151> *Pyrogen Test* (2018)
 - FDA Guidance, Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process, June 2016
 - FDA Guidance, *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters*, March 1995.

Performance Bench Testing

The Merit RadialFlo Arterial Catheter complies with the FDA recognized consensus standards ISO 10555-1 and ISO 10555-5, as outlined within this submission. Results of the testing demonstrate that the subject device met the acceptance criteria sufficient for its intended use. Testing included the following from these standards:

ISO 10555-1	
Radio-detectability	Freedom from Leakage
Biocompatibility	Hubs (reference to ISO 80369-7)
Surface	Flowrate
Corrosion Resistance	Distal Tip
Peak Tensile Force	Designation of nominal size
ISO 10555-5	
Colour Code	Needle
Catheter Unit	Vent Fitting

Biocompatibility testing

The biocompatibility evaluation for the Merit RadialFlo Arterial Catheter was conducted in accordance with the FDA Guidance Document “Use of International Standard ISO 10993-1, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process,’” June 16, 2016, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. Testing included the following:

- Cytotoxicity
 - Sensitization
 - Intracutaneous
 - Acute Systemic Toxicity
 - Pyrogenicity
 - Hemocompatibility
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	The Merit RadialFlo Arterial Catheter is an externally communicating device with circulating blood contacting for prolonged duration (> 24h to 30d).
Summary of Substantial Equivalence	Based on the indications for use, design, safety and performance testing, the subject Merit RadialFlo Arterial Catheter meets the requirements of all the applicable standards including the FDA recognized consensus standards that are considered essential for its intended use and is substantially equivalent to the predicate device (K151698), the BD Angiocath™ IV Catheter. The difference in technology, design and materials used are supported by the reference device (K850460), the Merit Secalon T Catheter (previously named as Viggo Secalon T) currently manufactured by Merit Medical Singapore Pte. Ltd.