



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
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August 27, 2015

Merit Medical Systems, Inc.  
Alina Stubbs  
Regulatory Affairs Specialist II  
65 Great Valley Parkway  
Malvern, Pennsylvania 19355

Re: K152116

Trade/Device Name: 5.5 F Worley Advanced LVI Lateral Vein Introducer  
Regulation Number: 21 CFR 870.1340  
Regulation Name: Catheter Introducer  
Regulatory Class: Class II  
Product Code: DYB  
Dated: July 29, 2015  
Received: July 30, 2015

Dear Alina Stubbs:

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

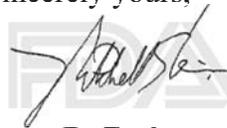
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, light-colored watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

**Indications for Use**

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

510(k) Number (if known)  
K152116

Device Name  
5.5 F Worley Advanced LVI Lateral Vein Introducer

Indications for Use (Describe)  
For the introduction of various types of pacing or defibrillator leads and catheters.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

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## 510(k) Summary

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<b>General Provisions</b>	Correspondent Name:	Merit Medical Systems, Inc.
	Address:	65 Great Valley Parkway Malvern, PA 19355
	Telephone Number:	(610) 651-5046
	Fax Number:	(801) 545-4285
	Contact Person:	Alina Stubbs
	Date of Preparation:	July 29, 2015
Registration Number:	2529252	

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<b>Subject Device</b>	Trade Name:	5.5 F Worley Advanced LVI Lateral Vein Introducer
	Common/Usual Name:	Sheath Introducer
	Classification Name:	Introducer, Catheter (21 CFR §870.1340)

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<b>Predicate Device</b>	Trade Name:	Coronary Sinus Guide and Lateral Vein Introducer Kits
	Classification Name:	Introducer, Catheter (21 CFR §870.1340)
	Premarket Notification:	K120158
	Manufacturer:	Merit Medical Systems, Inc. 65 Great Valley Parkway Malvern, PA 19355 (formerly operating as Thomas Medical Products, Inc.)

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<b>Classification</b>	Class II
	21 CFR §870.1340
	FDA Product Code: DYB
	Review Panel: Cardiovascular

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<b>Intended Use</b>	For the introduction of various types of pacing or defibrillator leads and catheters.
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**Device  
Description**

The 5.5 F Worley Advanced LVI Lateral Vein Introducer is intended to access the coronary venous system either alone or in a telescopic assembly with other devices. The 5.5 F Worley Advanced LVI Lateral Vein Introducer serve as a conduit to guide devices, including guidewires, pacemaker or defibrillator leads, and catheters, or to deliver contrast medium into specific branches of the coronary venous system. They have direct contact to the inner heart. 5.5 F Worley Advanced LVI Lateral Vein Introducers come with various curve configurations to facilitate sub-selective access to angulated lateral vein branches. 5.5 F Worley Advanced LVI Lateral Vein Introducers are designed as single use devices and for short term application (< 24 hours). Only medical doctors and medical personnel, who are well trained in cardiology, should apply these introducers.

The 5.5 F Worley Advanced LVI Lateral Vein Introducers have a shaft design with two (2) stiffness segmentations. The shaft is reinforced by a metal braid from the proximal end until approximately 0.130 inches from the distal end. The shaft is coated by a medical-grade coating that provides enhanced lubricity when advanced through the Coronary Sinus Guide Introducer.

The proximal end of the 5.5 F Worley Advanced LVI Lateral Vein Introducers are equipped with a hemostasis valve that reduces the risk of blood loss and air embolism and a side-port with 3-way stopcock to allow fluid infusion and contrast injection.

There are various versions of the introducer curves that are used according to the anatomy of the present coronary vasculature. The distal soft tip has a radius on the outer diameter and the distal tip further contains a polymeric x-ray marker for enhanced visibility under fluoroscopy.

The materials of construction are primarily polymers.

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Summary of the technological characteristics of the modified device compared to the predicate devices:

<b>Technical Characteristics</b>	<b>Predicate Device K120158</b>	<b>Subject Device</b>
Hemostasis valve provided	Yes	Yes
Compatible with .038" guide wire	Yes	Yes
Lengths:	62 cm	66cm
French sizes:	7 F I.D.	5.5 F I.D.
Curves:	0 to 180 degree, single or compound curves	0 to 180 degree, single or compound curves
Sheath introducer break-away hemostasis valve	Yes	Yes
Wire braid reinforcement completely encapsulated	Yes	Yes
Radiopaque tip	Yes	Yes
Side port for infusion and contrast injection	Yes	Yes
UV & heat stabilizers	Yes	Yes
Stiffness segmentations	3	2
<b>Device Materials</b>	The materials of construction are primarily polymers.	The materials of construction are primarily polymers.

The 5.5 F Worley Advanced LVI Lateral Vein Introducer has been thoroughly tested through verification of product specifications and user requirements. The following quality assurance measures were applied during the development of the 5.5 F Worley Advanced LVI Lateral Vein Introducer:

**Safety &  
Performance  
Tests**

- Risk Analysis
- Requirements/Specification Reviews
- Design Reviews
- Performance Testing (Verification) including but not limited to:
  - Dimensional Tests
    - Sheath introducer Curve dimensions
    - Sheath introducer outer diameter (O.D.)
    - Sheath introducer inner diameter (I.D.)
    - Sheath introducer free length, overall length
    -
  - Functional Tests
    - Sheath introducer soft tip joint integrity
    - Sheath introducer valve housing separation
    - Sheath introducer tube/valve housing pull force
    - Sheath introducer radiopaque tube segment joint pull force
    - Sheath introducer tube joint pull force
  - Simulated Use Test
    - Sheath introducer tube slitting with slit
    - Sheath introducer radiopaque tip bend
  - Visual Tests
    - Kit pouch integrity
    - Kit package integrity
    - Sheath Introducer visual appearance
    - Guiding catheter visual appearance
    - TVI visual appearance
    - Slitter (Cutter) visual appearance
- Sterilization Validation
- Biocompatibility Testing
  - Cytotoxicity

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No performance standards have been established under section 514 of the Food, Drug and Cosmetic Act for this device. Performance testing of the 5.5 F Worley Advanced LVI Lateral Vein Introducer was conducted based on the risk analysis and based on the requirements of the following international standards:

**International Standards**

- ISO 11070: 1998(E), Sterile, single-use intravascular catheter introducers
- 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 TIR28:2009, Product adoption and process equivalence for ethylene oxide sterilization
- ISO 10993-1: 2009, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing within a risk management process,
- ISO 10993-7: 2008, Biological Evaluation of Medical Devices Part-7 Ethylene Oxide Sterilization Residuals
- ISO 10993-17: 2002, Biological evaluation of medical devices – Part 17: Methods for the establishment of allowable limits for leachable substances
- ASTM D4169-09, Standard Practice for Performance Testing of Shipping Containers and Systems
- ISO 11607-1: 2009, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 14971:2012, Medical devices – Application of risk management to medical devices

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**Summary of Substantial Equivalence**

Based on the indications for use, design, safety and performance testing, the subject 5.5 F Worley Advanced LVI Lateral Vein Introducer meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Coronary Sinus Guide and Lateral Vein Introducer Kits - K120158, manufactured by Merit Medical Systems, Inc..

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