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

April 5, 2017

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

Re: K170668

Trade/Device Name: Heartspan® Steerable Sheath Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: March 3, 2017
Received: March 6, 2017

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,

Fernando Aguel -S

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

Enclosure

4.0 Indications for Use

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)*

K170668

Device Name

HeartSpan® Steerable Sheath Introducer

Indications for Use *(Describe)*

The HeartSpan® Steerable Sheath Introducer is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

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.

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

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5.0 510(k) Summary

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Systems, Inc. 65 Great Valley Parkway Malvern, PA 19335 (610) 651-5046 (801) 545-4285 Alina Stubbs March 3, 2017 2529252
Subject Device	Trade Name: Common/Usual Name: Classification Name: Regulatory Class: Product Code: 21 CFR §: Review Panel:	HeartSpan® Steerable Sheath Introducer Sheath Introducer Introducer, Catheter II DYB 870.1340 Cardiovascular
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer: This predicate has not been subject to a design-related recall.	HeartSpan Steerable Introducer Kit Introducer, Catheter K132164 Merit Medical Systems, Inc.
Reference Device	No reference devices were used in this submission.	

Device Description	The HeartSpan® Steerable Sheath Introducer consists of a dilator, guide wire, and steerable sheath, which are designed for catheter introduction into the cardiac anatomy. The device is provided sterile (ethylene oxide) and intended for single use only. It is for use in hospitals or healthcare facilities. The HeartSpan® Steerable Sheath Introducer has three configurations; Small, Medium, and Large Curl (differing curve radii). The steerable sheath introducer contains a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A sideport with three-way stopcock is provided for air or blood aspiration, fluid infusion, blood sampling, and pressure monitoring. The sheath introducer handle includes a rotating knob to enable clockwise and counterclockwise tip deflection ≥180° with a radius of 16.4 – 50 mm nominal (measured at 180° deflection). The steerable sheath introducer also includes distal holes to facilitate aspiration and minimize cavitation, a radiopaque tip marker to improve fluoroscopic visualization, an atraumatic soft tip, and a lubricious coating on the outer surface. The dilator is designed to mate to the inner diameter of the sheath, and has a tapered tip. The guide wire is super-stiff with PTFE coating and J-tip. The guide wire maintains a percutaneous path through the skin and tissue over which the sheath/dilator assembly is tracked. The materials of construction are primarily polymers with the exception of stainless steel braid reinforcement and deflection wires in the sheath introducer shaft that are completely encapsulated in the sheath wall and do not contact the patient or bodily fluids.
Indications for Use	The HeartSpan® Steerable Sheath Introducer is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum. There is no change in the Indications for Use Statement from the predicate to the subject device other than the device trade name.

Comparison to Predicate Device

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

Key Technical Characteristics	Predicate Device (K132164)	Subject Device
Hemostasis valve provided	Yes	Yes
Dilator to Guide Wire Compatibility	up to 0.038”	up to 0.032”
Guide wire Design / Dimensions	Super-Stiff with PTFE 0.032” x 180cm	Super-Stiff with PTFE 0.032” x 180cm
Compatibility with Standard Transseptal Needle	Yes	Yes
Length	74 cm	74 cm
Labeled French size	8.6F	8.5F
Bi-Directional Curving	Yes ≥180° in both directions radius: 10 – 56 mm nominal (measured at 180° deflection)	Yes ≥180° in both directions radius: 16.4 – 50 mm nominal (measured at 180° deflection)
One-Handed Operation of Curving Mechanism	Yes	Yes
Wire braid reinforcement completely encapsulated	Yes	Yes
Radiopaque tip or marker	Yes	Yes
Soft Atraumatic Tip	Yes	Yes
Sheath neutral position indicator	molded visible indicators on steering knob and handle	addition of tactile neutral position indicator
Side port for infusion and contrast injection	Yes	Yes
Orientation of side port assembly	90° relative to sheath steering plane	parallel to sheath steering plane
Dilator Hub Curve Orientation Indicator	None	Printed raised arrow
Dilator Length	95cm	94cm
Labeled Dilator French Size	8.6F	8.5F
Dilator Curve	55º	55º

Safety & Performance Tests	The HeartSpan® Steerable Sheath 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 HeartSpan® Steerable Sheath Introducer:
	
	• Performance Testing-Bench
	  ○ Sheath & Dilator Tube Radiopacity
	  ○ Sheath Tube Flexural & Torsional Rigidity
	  ○ Sheath Tube O.D., I.D. & Free Length
	  ○ Sheath Curl Diameter
	  ○ Sheath Hemostasis / Air Leak Resistance
	  ○ Dilator Extension Length
	  ○ Sheath Neutral Position Tactile Indicator
	  ○ Sheath and Dilator Tip Integrity
	  ○ Sheath Bonded Joints Leak Resistance
	  ○ Sheath Valve Housing / Sideport Tube Joint Pull Force
	  ○ Sheath Tube Joint Pull Forces
	  ○ Dilator Hub & Tip I.D.
	  ○ Dilator Tip Wall Thickness
	  ○ Dilator Free & Overall Length
	  ○ Transseptal Needle Protrusion from Dilator Tip & from Dilator Hub
	  ○ Dilator Hub Mark Adherence
	  ○ Sheath/Dilator Attachment & Detachment Force
	  ○ Dilator Hub Luer Liquid Leakage, Air Leakage, Separation Force, Unscrewing Torque, Ease of Assembly, and Resistance to Overriding
	  ○ Dilator Hub Luer Stress Cracking
	  ○ Dilator Tip Integrity
	  ○ Dilator Hub/Tube Joint Pull Force
	  ○ Package Integrity
	  ○ Sheath, Dilator & Guidewire Visual Appearance after Transit Simulation
	• Biocompatibility Testing
	  ○ Cytotoxicity
	  ○ Sensitization
	  ○ Irritation / Intracutaneous
	  ○ Acute Systemic Toxicity
	  ○ Pyrogenicity
	  ○ Hemolysis
	  ○ Thrombogenicity
	  ○ Complement Activation

Safety & Performance Tests cont.	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject HeartSpan® Steerable Sheath Introducer was conducted based on the risk analysis and based on the requirements of the following international standard: • AAMI/ANSI ST72:2011, Bacterial Endotoxins – Test methods, routine monitoring, and alternatives to batch testing • AAMI TIR28:2009, Product adoption and process equivalence for ethylene oxide sterilization • ASTM D4169-09, Packaging Distribution Testing • ASTM F756-13, Standard Practice for Assessment of Hemolytic Properties of Materials. 2013 • ISO 10993-1:2009, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process, and FDA

guidance Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices, May 1, 1995

- ISO 10993-4:2002 (Amd.1:2006), Biological evaluation of medical devices – Part 4: Selection of tests for interaction with blood
- ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-7: 2008, Biological Evaluation of Medical Devices Part-7 Ethylene Oxide Sterilization Residuals
- ISO 10993-10:2010, Biological evaluation of medical devices – Part 10: Tests for irritation and delayed type hypersensitivity
- ISO 10993-11:2006, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
- ISO 11070:2014 Sterile single-use intravascular catheter introducers
- ISO 11135-1: 2007 Sterilization of health care products – routine control of a sterilization process for medical devices
- ISO 14971:2012, Medical devices – Application of risk management to medical devices
- ISO 15223-1: 2012, Medical Devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General Requirements
- 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 for testing
- ISO 594-1:1986, 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 a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings
- USP 39-NF 34 <151>, United States Pharmacopeia 39, National Formulary 34, 2016 <151> Pyrogen Test

The results of the testing demonstrated that the subject HeartSpan® Steerable Sheath Introducer met the predetermined acceptance criteria applicable to the safety and efficacy of the device.

Summary of Substantial Equivalence

Based on the indications for use, design, safety and performance testing, the subject HeartSpan® Steerable Sheath Introducer meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the HeartSpan Steerable Introducer Kit, K132164 manufactured by Merit Medical Systems, Inc.