September 11, 2017

Merit Medical Systems, Inc.
Jacquelyn Huyghue
Regulatory Affairs Specialist I
65 Great Valley Parkway
Malvern, Pennsylvania 19355

Re: K172117
   Trade/Device Name: Prelude Pursuit Splittable Sheath Introducer
   Regulation Number: 21 CFR 870.1340
   Regulation Name: Catheter Introducer
   Regulatory Class: Class II
   Product Code: DYB
   Dated: July 11, 2017
   Received: July 13, 2017

Dear Jacquelyn Huyghue:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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 (DICE) 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 (DICE) 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,

Nicole G. Ibrahim -S

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

Device Name
Prelude Pursuit™ Splittable Sheath Introducer

Indications for Use (Describe)
The introduction of various types of pacing/defibrillator leads and catheters into the venous vasculature.

Type of Use (Select one or both, as applicable)
- [x] 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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**510(k) Summary - K172117**

**Submitter Name:** Merit Medical Systems, Inc.
**Address:** 65 Great Valley Parkway
Malvern, PA 19355

**Telephone Number:** (610) 651-5090
**Fax Number:** (801) 545-4285
**Contact Person:** Jacquelyn Huyghue
**Date Prepared:** July 11, 2017
**Registration Number:** 2529252

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**Subject Device**

<table>
<thead>
<tr>
<th>Trade Name:</th>
<th>Prelude Pursuit™ Splittable Sheath Introducer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common/Usual Name:</td>
<td>Sheath Introducer</td>
</tr>
<tr>
<td>Classification Name:</td>
<td>Introducer, Catheter</td>
</tr>
<tr>
<td>Regulatory Class:</td>
<td>II</td>
</tr>
<tr>
<td>Product Code:</td>
<td>DYB</td>
</tr>
<tr>
<td>21 CFR §:</td>
<td>870.1340</td>
</tr>
<tr>
<td>Review Panel:</td>
<td>Cardiovascular</td>
</tr>
</tbody>
</table>

**Predicate Device**

<table>
<thead>
<tr>
<th>Trade Name:</th>
<th>St. Jude Medical SJM™ Peel Away Introducer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification Name:</td>
<td>Introducer, Catheter</td>
</tr>
<tr>
<td>Premarket Notification:</td>
<td>K791129</td>
</tr>
<tr>
<td>Manufacturer:</td>
<td>St. Jude Medical (formerly Diag Corp.)</td>
</tr>
</tbody>
</table>

This predicate has not been subject to a design-related recall.

**Reference Device**

No reference devices were used in this submission.

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**Device Description**

The Prelude Pursuit™ Splittable Sheath Introducer is a splittable introducer system indicated for the introduction of various types of pacing/defibrillator leads and catheters into the venous vasculature. The "splittable" function allows the introducer to be withdrawn over a diagnostic/therapeutic catheter (e.g. peripherally inserted central catheter, totally implantable venous access device/port, dialysis, drainage, hemodynamic line, etc.) or pacing/defibrillator lead and from the vessel while maintaining said device in place. The product is available in 16 French sizes, from 5 F through 16 F, and in two different lengths, 13 cm and 25 cm. It is packaged either as a kit with optional accessory components (introducer needle, syringe, guide wire), or as a stand-alone (sheath-dilator) set. The device is provided sterile and intended for single use only. It is for use in hospitals or healthcare facilities.

The splittable sheath introducer is lubricated with a silicone dispersion and its hub has a threaded locking mechanism for dilator engagement. The dilator is designed to conform to the inner diameter of the introducer and has a tapered tip for ease of insertion.
Prelude Pursuit™ Splittable Sheath Introducer kit consists of:

- One (1) Splittable Sheath Introducer
- One (1) Dilator
- One (1) .038” x 50 cm or .038” x 80 cm guidewire (depending on the introducer length)
- One (1) 18 G introducer needle
- One (1) 12 cc or 10 cc syringe

Prelude Pursuit™ Splittable Sheath Introducer stand-alone set consists of:

- One (1) Splittable Sheath Introducer
- One (1) Dilator

The materials of construction are primarily polymers except for the optional guide wire and introducer needle cannula, which are stainless steel.

| Indications for Use | The introduction of various types of pacing/defibrillator leads and catheters into the venous vasculature. |
Summary of the technological characteristics of the modified device compared to the predicate devices:

<table>
<thead>
<tr>
<th>Technical Characteristics</th>
<th>Predicate Device (K791129)</th>
<th>Subject Device Prelude Pursuit™ Splittable Sheath Introducer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device Dimensions (nominal)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sheath introducer inner diameter (French)</td>
<td>5 F through 16 F</td>
<td>5 F through 16 F</td>
</tr>
<tr>
<td>Sheath introducer length (cm)</td>
<td>14 &amp; 23 cm</td>
<td>13 &amp; 25 cm</td>
</tr>
<tr>
<td>Dilator outer diameter (French)</td>
<td>5 F through 16 F</td>
<td>5 F through 16 F</td>
</tr>
<tr>
<td>Dilator length (in)</td>
<td>14 cm: 8.67” and 23 cm: 12.01”</td>
<td>13 cm: 7.59” and 25 cm: 12.34”</td>
</tr>
<tr>
<td>Dilator tip ID (in)</td>
<td>0.040”</td>
<td>0.039”</td>
</tr>
<tr>
<td>Introducer needle length (cm)</td>
<td>6.6 cm</td>
<td>7 cm</td>
</tr>
<tr>
<td>Introducer needle outer diameter (gauge)</td>
<td>18 G</td>
<td>18 G</td>
</tr>
<tr>
<td>Guide wire length &amp; diameter (in. x cm)</td>
<td>14 cm: 0.038” x 50 cm J-Tip and 23 cm: 0.038” x 80 cm J-Tip</td>
<td>13 cm: 0.038” x 50 cm J-Tip and 25 cm: 0.038” x 80 cm J-Tip</td>
</tr>
<tr>
<td>Syringe volume (cc)</td>
<td>12 cc</td>
<td>12 cc or 10 cc</td>
</tr>
</tbody>
</table>

**Device Materials**

- The materials of construction are primarily polymers with the exception of the guide wire and needle cannula, which are stainless steel.
- The materials of construction are primarily polymers with the exception of the guide wire and needle cannula, which are stainless steel.

Note: All dimensions are nominal.
No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the Prelude Pursuit™ Splittable Sheath Introducer was conducted based on the risk analysis and based on the requirements of the following international standards:

- ISO 11070:2014 Sterile single-use intravascular catheter introducers
- ISO 594-2:1998, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings
- ISO 11135-1: 2007 Sterilization of health care products – routine control of a sterilization process for medical devices
- AAMI TIR28:2009, Product adoption and process equivalence for ethylene oxide sterilization
- ISO 10993-4:2017, Biological Evaluation of Medical Devices Part 4: Selection of tests for interactions with blood
- 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
- United States Pharmacopeia 40, National Formulary 35, 2017 <151> Pyrogen Test
- ASTM D4169-16:2016, Standard Practice for Performance Testing of Shipping Containers and Systems
- ISO 15223-1: 2016, Medical Devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General Requirements
- 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 14971:2012, Medical devices – Application of risk management to medical devices
• ASTM F2096-11:2011, Standard Test Method for Detecting Gross Leaks in Packaging by Internal pressurization (Bubble Test)
• ASTM F1140-07:2007 Standard Test Methods for internal Pressurization Failure Resistance of Unrestrained Packages

The Prelude Pursuit™ Splittable Sheath Introducer has been thoroughly tested through verification of product specifications and user requirements. The following quality assurance and performance measures were applied during the development of the Prelude Pursuit™ Splittable Sheath Introducer:

• Risk Analysis
• Requirements/Specification Reviews
• Design Reviews
• Performance Testing (Verification):
  o Dimensional Tests
    ▪ Introducer sheath tube outer diameter (OD)
    ▪ Introducer tip inner diameter (ID)
    ▪ Introducer free length
    ▪ Dilator tube outer diameter (OD)
    ▪ Dilator tip inner diameter (ID)
    ▪ Dilator protrusion from introducer when assembled
  o Functional Tests
    ▪ Introducer hub break force
    ▪ Introducer sheath peel force
    ▪ Introducer tube to hub joint strength
    ▪ Dilator tube to hub joint strength
    ▪ Mating dilator ISO 594-2 compliance
  o Simulated Use Test
    ▪ Introducer sheath / dilator insertion – synthetic tissue
    ▪ Sheath – dilator assembly – kink & flexibility
    ▪ Mating dilator to introducer engagement
  o Visual Tests
    ▪ Introducer soft touch pad attachment

• Sterilization validation

• Biocompatibility
  o Cytotoxicity
  o Sensitization
  o Irritation
  o Acute Systemic Toxicity
  o Pyrogenicity
  o Hemolysis

Performance
Data cont.
Summary of Substantial Equivalence

Based on the indications for use, design, safety and performance testing, the subject Prelude Pursuit™ Splittable Sheath Introducer meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the St. Jude Medical SJM™ Peel Away Introducer (K791129).