## 510(k) Summary

<table>
<thead>
<tr>
<th>Correspondent Name:</th>
<th>Merit Medical Systems, Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>65 Great Valley Parkway</td>
</tr>
<tr>
<td></td>
<td>Malvern, PA 19355</td>
</tr>
<tr>
<td>Telephone Number:</td>
<td>(610) 651-5046</td>
</tr>
<tr>
<td>Fax Number:</td>
<td>(801) 545-4285</td>
</tr>
<tr>
<td>Contact Person:</td>
<td>Alina Stubbs</td>
</tr>
<tr>
<td>Date of Preparation:</td>
<td>August 23, 2013</td>
</tr>
<tr>
<td>Registration Number:</td>
<td>2529252</td>
</tr>
</tbody>
</table>

### Subject Device

<table>
<thead>
<tr>
<th>Trade Name:</th>
<th>HeartSpan™ Fixed Curve Braided Transseptal Sheath</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common/Usual Name:</td>
<td>Transseptal Introducer Kit</td>
</tr>
<tr>
<td>Classification Name:</td>
<td>Catheter Introducer (21 CFR §870.1340)</td>
</tr>
</tbody>
</table>

### Predicate Device

<table>
<thead>
<tr>
<th>Trade Name:</th>
<th>HeartSpan™ Fixed Curve Braided Transseptal Sheath</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification Name:</td>
<td>Catheter Introducer (21 CFR §870.1340)</td>
</tr>
<tr>
<td>Premarket Notification:</td>
<td>K004026 – Braided Guiding Introducer</td>
</tr>
<tr>
<td>Manufacturer:</td>
<td>Merit Medical Systems, Inc.</td>
</tr>
<tr>
<td></td>
<td>65 Great Valley Parkway</td>
</tr>
<tr>
<td></td>
<td>Malvern, PA 19355</td>
</tr>
<tr>
<td></td>
<td>(formerly operating as Thomas Medical Products, Inc.)</td>
</tr>
</tbody>
</table>

### Classification

- Class II
- 21 CFR §870.1340
- FDA Product Code: DYB
- Review Panel: Cardiovascular

### Intended Use

The HeartSpan™ Fixed Curve Braided Transseptal Sheath is indicated "For the percutaneous introduction of various types of cardiovascular catheters to all heart chambers, including the left atrium via transseptal puncture."

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The modified HeartSpan™ Fixed Curve Braided Transseptal Sheath consists of a dilator, guidewire, and fixed curve 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 fixed curve introducer contains a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A side-port with three-way stopcock is provided for air or blood aspiration, fluid infusion, blood sampling, and pressure monitoring. The introducer is available in lengths ranging from 60 to 101.5 cm and curve configurations from 15° to 150° to address various anatomical features. The fixed curve introducer also includes distal perfusion 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 inner and outer surfaces. The dilator is designed to conform to the inner diameter of the sheath, and has a tapered tip.

The materials of construction are primarily polymers with the exception of stainless steel braid reinforcement wires in the introducer shaft that are completely encapsulated in the sheath wall and do not contact the patient or bodily fluids.

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

<table>
<thead>
<tr>
<th>Technical Characteristics</th>
<th>Predicate Device (K004026)</th>
<th>Modified Device (K132720)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemostasis valve provided</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Dilator to Guide wire</td>
<td>up to 0.038&quot;</td>
<td>up to 0.038&quot;</td>
</tr>
<tr>
<td>Compatibility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compatibility with Standard Transseptal Needle</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Length</td>
<td>30 cm min.</td>
<td>60 - 101.5 cm</td>
</tr>
<tr>
<td>French size</td>
<td>8.5F &amp; 9.5F</td>
<td>8.5F</td>
</tr>
<tr>
<td>Curve</td>
<td>0° - 180°</td>
<td>15° - 150°</td>
</tr>
<tr>
<td>Wire braid reinforcement</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>completely encapsulated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiopaque tip or marker</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Soft Atraumatic Tip</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Side port for infusion and contrast injection</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>UV and Thermal Stabilization in Sheath Tube and Tip</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Distal perfusion holes</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>
No performance standards have been established under section 514 of the Food, Drug and Cosmetic Act for this device. Performance testing of the modified HeartSpan™ Fixed Curve Braided Transseptal Sheath was conducted based on the risk analysis and based on the requirements of the following international standards:

- 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 Skin Sensitization

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The modified HeartSpan™ Fixed Curve Braided Transseptal Sheath has been thoroughly tested through verification of product specifications and user requirements. The following quality assurance measures were applied during the development of the modified HeartSpan™ Fixed Curve Braided Transseptal Sheath:

- Risk Analysis
- Requirements/Specification Reviews
- Design Reviews
- Sterilization validation (ethylene oxide)
- Biocompatibility Testing (Verification)
- Performance Testing (Verification) listed below:
  - Sheath Tube Inner Diameter
  - Sheath Tube Outer Diameter
  - Sheath Free Length
  - Sheath Tip Inner Diameter
  - Sheath Visual Inspection
    - Curve Orientation
    - Sheath Curve Form
    - Breakaway Flash
    - Protruding wires or marker band
    - Tip Defects
    - Bumps or protrusion on tube
  - Sheath tip transition to dilator
  - Visual inspection of sheath inner surface
  - Simulated Use Test
  - Valve housing to tube joint integrity
  - Sheath Tube Delamination
  - Sheath Tip Integrity
  - Sheath Tip to Tube Joint Integrity
  - Sheath Tip Bend Back

The results of the testing demonstrated that the modified HeartSpan™ Fixed Curve Braided Transseptal Sheath meets the predetermined acceptance criteria applicable to safety and efficacy of the device.

Merit Medical Systems, Inc. considers the modified HeartSpan™ Fixed Curve Braided Transseptal Sheath substantially equivalent to the currently marketed predicate device (Braided Guiding Introducer - K004026). This assessment is based upon analysis of similar technological characteristics, bench testing, and indications for use.
February 12, 2014

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

Re: K132720
  Trade Name: HeartSpan™ Fixed Curve Braided Transseptal Sheath
  Regulation Number: 21 CFR 870.1340
  Regulation Name: Catheter Introducer
  Regulatory Class: Class II
  Product Code: DYB
  Dated: January 10, 2014
  Received: January 13, 2014

Dear Ms. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

[Signature]

for Bram D. 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): K132720

Device Name: HeartSpan™ Fixed Curve Braided Transseptal Sheath

Indications for Use:

For the percutaneous introduction of various types of cardiovascular catheters to all heart chambers, including the left atrium via transseptal puncture.

Prescription Use X AND/OR Over-The-Counter-Use
(Per 21 CFR 801 Subpart D) (Per 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)

[Signature] FDA