September 7, 2017

XableCath, Inc.
Mr. Rick Gaykowski
Chief Regulatory Officer
417 S. Wakara Way, Suite 3510
Salt Lake City, UT 84108

Re: K170041
  Trade/Device Name: XableCath Support Catheter
  Regulation Number: 21 CFR 870.1250
  Regulation Name: Percutaneous Catheter
  Regulatory Class: Class II
  Product Code: DQY
  Dated: July 19, 2017
  Received: July 24, 2017

Dear Mr. Gaykowski:

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,

Kenneth J. Cavanaugh -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
XableCath Support Catheter

510(k) Number (if known)
K170041

Indications for Use (Describe)
The XableCath catheter is intended to be used to facilitate access to discrete regions of the peripheral vasculature in conjunction with steerable guidewires. This device may be used to facilitate placement and exchange of guidewires and other interventional devices.

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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Department of Health and Human Services
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Office of Chief Information Officer
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XableCath Support Catheter

Date prepared: August 28, 2017

Submitter information [21 CFR 807.929(a)(1)]

Name: XableCath, Inc.
Address: 417 S. Wakara Way, Ste 3510, Salt Lake City, Utah 84108-1457
Phone Number: (617) 447-4000 Mobile
Fax number: N/A
Establishment Registration Number: Yet to be secured
Name of contact person: Rick Gaykowski, Chief Regulatory Officer

Name of the device [21 CFR 807.92(a)(2)]

Trade or proprietary name: XableCath Support Catheter
Common or usual name: Peripheral Vascular Support Catheter
Classification name: Percutaneous Catheter
Classification number: 21 CFRR 870.1250, Procode DQY

Legally marketed device(s) to which equivalence is claimed [21 CFR 807.92(a)(3)]

Merit Medical SureCross® Catheter (K123311)

Device description [21 CFR 807.92(a)(4)]

The XableCath Support Catheter device is an over-the-wire (OTW) single-lumen catheter, with blunt tip design. The catheter is offered in a product family configuration, with size models as outlined in the table below:

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>French Size</th>
<th>Working Length (cm)</th>
<th>Recommended Guidewire Inches (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>XC-014-065B</td>
<td>5Fr</td>
<td>65</td>
<td>0.014” (0.36 mm)</td>
</tr>
<tr>
<td>XC-014-090B</td>
<td>5Fr</td>
<td>90</td>
<td>0.014” (0.36 mm)</td>
</tr>
<tr>
<td>XC-014-145B</td>
<td>5Fr</td>
<td>145</td>
<td>0.014” (0.36 mm)</td>
</tr>
<tr>
<td>XC-018-065B</td>
<td>6Fr</td>
<td>65</td>
<td>0.018” (0.46 mm)</td>
</tr>
<tr>
<td>XC-018-090B</td>
<td>6Fr</td>
<td>90</td>
<td>0.018” (0.46 mm)</td>
</tr>
<tr>
<td>XC-018-145B</td>
<td>6Fr</td>
<td>145</td>
<td>0.018” (0.46 mm)</td>
</tr>
<tr>
<td>XC-035-065B</td>
<td>7Fr</td>
<td>65</td>
<td>0.035” (0.89 mm)</td>
</tr>
<tr>
<td>XC-035-090B</td>
<td>7Fr</td>
<td>90</td>
<td>0.035” (0.89 mm)</td>
</tr>
<tr>
<td>XC-035-145B</td>
<td>7Fr</td>
<td>145</td>
<td>0.035” (0.89 mm)</td>
</tr>
</tbody>
</table>
The catheter shaft consists of a cortically reinforced co-polymeric material blend, with radiopaque cobalt chromium-tungsten-nickel distal tip. The proximal portion is comprised of an olefin strain relief and polycarbonate hub, which includes a female luer connection communicating with the catheter lumen. The catheter pass-through lumen is used to advance the catheter over an appropriately sized guidewire for intravascular advancement to the target site. Component connections are ensured through inter-mechanical locks and utilization of medical grade adhesives. Catheter guidewire compatibility size/length are declared on the XableCath Support Catheter strain relief. All provided family member models are compatible with ≥4Fr introducer sheaths. All configurations are provided sterile, single-use only.

**Indications for Use [21 CFR 807.92(a)(5)]**

The XableCath catheter is intended to be used to facilitate access to discrete regions of the peripheral vasculature in conjunction with steerable guidewires. This device may be used to facilitate placement and exchange of guidewires and other interventional devices.

**Comparison of the technological characteristics with the predicate device [21 CFR 807.92(a)(6)]**

The subject devices and predicate devices are based on the following similar technological elements:

The XableCath Support Catheter indication for use is comparable to the predicate device, with direct overlap for peripheral application. Both device systems provide support access to the vasculature, utilize similar insertion and deployment principles, and allow for guidewire and other interventional device exchanges. Both products are for use in endovascular catheter utilization and deployment. Both products are configured with uniquely design distal tip regions for intravascular passage across stenotic regions. Furthermore, both catheters possess similarly offered working lengths, and identical dimensional guidewire compatibility (i.e., 0.014", 0.018", and 0.035").

Both products have similar intended therapeutic applications, used in similar patient populations, and employ equivalent technological characteristics in achieving desired technical methods-of-action through manual advancement under fluoroscopic imaging. Similar categories of product materials comprise the subject and predicate products, with both containing hub/luer, shaft body, and distal tip design regions.

The following table illustrates comparable features of the subject and predicate products:

<table>
<thead>
<tr>
<th>Product Information</th>
<th>Subject XableCath Support Catheter</th>
<th>Predicate Merit Medical SureCross® Catheter</th>
</tr>
</thead>
<tbody>
<tr>
<td>510(k) #</td>
<td>TBD</td>
<td>K123311</td>
</tr>
<tr>
<td>FDA Classification</td>
<td>Class II</td>
<td>Class II</td>
</tr>
<tr>
<td>Regulation Number</td>
<td>870.1250</td>
<td>870.1250</td>
</tr>
<tr>
<td>Product Code</td>
<td>DQY</td>
<td>DQY</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>The XableCath catheter is intended to be used to facilitate access to discrete regions of the peripheral vasculature in conjunction with steerable guidewires. This device may be used to facilitate placement and exchange of guidewires and other interventional devices.</td>
<td>The Access &amp; Support Catheter is intended for use during coronary and peripheral interventional procedures to guide and support guidewires, traverse discrete portions of the vasculature, allow for guidewire exchange and provide a conduit for infusion of saline solution, diagnostic contrast agents and therapeutic agents.</td>
</tr>
<tr>
<td><strong>Proximal Luer/Hub</strong></td>
<td><strong>HDPE</strong></td>
<td><strong>HDPE</strong></td>
</tr>
<tr>
<td>------------------------</td>
<td>----------</td>
<td>----------</td>
</tr>
<tr>
<td><strong>Strain Relief</strong></td>
<td>Olefin</td>
<td>PEBA</td>
</tr>
<tr>
<td><strong>Catheter Shaft</strong></td>
<td>Nylon, Single lumen</td>
<td>HDPE, Single lumen</td>
</tr>
<tr>
<td><strong>Markers</strong></td>
<td>Cobalt-chromium/SS</td>
<td>Pt/Ir</td>
</tr>
<tr>
<td><strong>Coating</strong></td>
<td>N/A</td>
<td>Hydrophilic</td>
</tr>
<tr>
<td><strong>Infusion Pressure/Burst Strength</strong></td>
<td>≥300 psi</td>
<td>≥300 psi</td>
</tr>
<tr>
<td><strong>Outer Diameter</strong></td>
<td>Varies by Model</td>
<td>Varies by Model</td>
</tr>
<tr>
<td>Proximal: 0.043&quot;, 0.053&quot;, 0.062&quot;</td>
<td>Proximal: 0.039&quot;, 0.044&quot;, 0.063&quot;</td>
<td></td>
</tr>
<tr>
<td>Distal: 0.060&quot;, 0.070&quot;, 0.080&quot;</td>
<td>Distal: 0.0265&quot;, 0.0305&quot;, 0.0505&quot;</td>
<td></td>
</tr>
<tr>
<td>Tip: 0.052&quot;, 0.063&quot;, 0.071</td>
<td>Tip: 0.0195&quot;, 0.0225&quot;, 0.0405&quot;</td>
<td></td>
</tr>
<tr>
<td><strong>Guidewire Compatibility</strong></td>
<td>0.014&quot;, 0.018&quot;, 0.035&quot;</td>
<td>0.014&quot;, 0.018&quot;, 0.035&quot;</td>
</tr>
<tr>
<td><strong>Guide Catheter (max)</strong></td>
<td>≥4Fr</td>
<td>5Fr</td>
</tr>
<tr>
<td><strong>Access Sheath (max)</strong></td>
<td>≥4Fr</td>
<td>5Fr</td>
</tr>
<tr>
<td><strong>Effective Working Length</strong></td>
<td>65, 90, 145cm</td>
<td>65, 90, 135, 150cm</td>
</tr>
<tr>
<td><strong>Deployment</strong></td>
<td>OTW – Manual</td>
<td>OTW - Manual</td>
</tr>
<tr>
<td><strong>Sterilization Method</strong></td>
<td>Gamma (SAL – 10^-6)</td>
<td>EO (SAL – 10^-6)</td>
</tr>
<tr>
<td><strong>Single Use, Sterile</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Packaging</strong></td>
<td>Sterile thermal sealed Tyvek/PET Pouch, SBS Carton</td>
<td>Sterile thermal-sealed Pouch, SBS Carton</td>
</tr>
<tr>
<td><strong>Use Environment</strong></td>
<td>Rx Only – By or on the order of a physician. Hospital, Lab/Surgical Suite</td>
<td>Rx Only – By or on the order of a physician. Hospital, Lab/Surgical Suite</td>
</tr>
</tbody>
</table>

The following technological differences exist between the subject and predicate devices:

- The subject and predicate devices have slightly differing distal tip configurations, unique to their particular design,
and overall product composition. Nevertheless, both product distal tip designs are intended to achieve the same outcomes and have been shown to be commensurate in performance through comparative assessment.

- The predicate product contains an exterior hydrophilic coating over the distal 40cm of length, whilst the subject product does not. Nevertheless, ease of insertion and tracking within applied models yields equivalent product delivery performance through comparative assessment.

- The predicate product is indicated for coronary application, and for delivery of diagnostic/therapeutic solutions, whilst the subject product is not.

Despite these noted differences between the subject and predicate products, these attributes are determined to be cumulatively insignificant as demonstrated through direct product comparative assessment.

### Performance Data [21 CFR 807.92(b)]

#### Summary of non-clinical tests conducted for determination of substantial equivalence [21 CFR 807.92(b)(1)]

- Direct product bench *in-vitro* comparison testing has shown the subject & predicate products to be substantially equivalent, via assessment within the following areas:
  - Visual & technical inspections
  - Luer syringe compatibility
  - Sheath compatibility
  - Guidewire retraction/reinsertion
  - Relative radiopacity comparison
  - Torque transmission & capability
  - Simulated use (iliac model)
  - Dimensional assessment & comparisons
  - Guidewire compatibility
  - Leak Testing
  - Catheter kink-resistance
  - Tensile testing (proximal & distal)
  - Corrosion testing
  - General packaging, shelf-life/expiry

- Full panel biocompatibility was successfully performed in accord with product classification, under GLP rigors, demonstrating that all utilized materials and methods of construction/processing passed biocompatibility rigors. Conducted test included:
  - Cytotoxicity
  - Irritation/Intracutaneous Reactivity
  - Hemolysis
  - Complement Activation
  - Platelet and Leukocyte Count
  - Sensitization
  - Systemic Toxicity (Acute)
  - Thromboresistance
  - Partial Thromboplastin Time
  - Materials Mediated Pyrogenicity

- Packaging integrity, transport challenge testing, and shelf-life testing were applied and successfully completed in accordance with established acceptance criteria demonstrating configurational adequacy.

### Summary of clinical tests conducted for determination of substantial equivalence or of clinical information [21 CFR 807.92(b)(2)]

No clinical tests were necessary. However human factors engineering and usability assessments were performed.

### Conclusions drawn [21 CFR 807.92(b)(3)]

Based upon the overlapping intended use, basal product designs, methods of deployment, target population and anatomical site overlap, and direct bench comparative assessment the preponderance of gathered evidence within this pre-market notification application demonstrates the XableCath Support Catheter has been shown to be substantially equivalent to the predicate device. Furthermore, the XableCath Support Catheter raises no new questions of safety or effectiveness when compared directly to the predicate device, and is therefore justifiably concluded to be substantially equivalent for declared intended use.