May 15, 2018

XableCath, Inc.
Mr. Rick Gaykowski
Chief Regulatory Officer
417 South Wakara Way, Suite 3510
Salt Lake City, Utah 84108-1457

Re: K180986
Trade/Device Name: XableCath Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: April 7, 2018
Received: April 16, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K180986

Device Name
XableCath Support Catheter

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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"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."*

# 510(k) SUMMARY
# XableCath™ Support Catheter

| **Submitter Information [21 CFR 807.929(a)(1)]** | |
|---|---|
| **Name** | XableCath, Inc. |
| **Address** | 417 S Wakara Way, Suite 3510<br>Salt Lake City, UT 84108-1457<br>USA |
| **Phone number** | 617-447-4000 Mobile |
| **Fax number** | N/A |
| **Establishment Registration Number** | Yet to be secured |
| **Name of contact person(s)** | Rick Gaykowski, Chief Regulatory Officer, Primary<br>Lisa Dunlea, Pres/CEO, Secondary |
| **Date prepared** | April 7, 2018 |
| **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** | Class II |
| **Regulation** | 21 CFR 870.1250 |
| **Product Code(s)** | DQY |
| **Legally marketed device(s) to which equivalence is claimed [21 CFR 807.92(a)(3)]** | XableCath Support Catheter, cleared under 510(k) K170041 |
| **Device description [21 CFR 807.92(a)(4)]** | Catheter, Percutaneous |
| **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. |

| **Summary of the technological characteristics of the device compared to the predicate device [21 CFR 807.92(a)(6)]** | | |
|---|---|---|
| **Feature** | **Subject Device: XableCath Support Catheter** | **Predicate Device: XableCath Support Catheter** |
| **Proximal Luer/Hub** | HDPE | HDPE |

| | | |
|---|---|---|
| **Strain Relief** | Olefin | Olefin |
| **Catheter Shaft** | Nylon, Single lumen | Nylon, Single lumen |
| **Markers** | Cobalt-chromium/SS | Cobalt-chromium/SS |
| **Distal Tip** | Abrasion | Blunt |
| **Distal Tip Material** | Cobalt chromium alloy | Cobalt chromium alloy |
| **Coating** | N/A | N/A |
| **Infusion Pressure/Burst Strength** | ≥300 psi | ≥300 psi |
| **Outer Diameter** | Varies by Model<br>Proximal: 0.043”, 0.053”, 0.062”<br>Distal: 0.060”, 0.070”, 0.080”<br>Tip: 0.052”, 0.063”, 0.071 | Varies by Model<br>Proximal: 0.043”, 0.053”, 0.062”<br>Distal: 0.060”, 0.070”, 0.080”<br>Tip: 0.052”, 0.063”, 0.071 |
| **Guidewire Compatibility** | 0.014”, 0.018”, 0.035” | 0.014”, 0.018”, 0.035” |
| **Guide Catheter (max)** | ≥4Fr | ≥4Fr |
| **Access Sheath (max)** | ≥4Fr | ≥4Fr |
| **Effective Working Length** | 65, 90, 145cm | 65, 90, 145cm |
| **Deployment** | OTW – Manual | OTW – Manual |
| **Sterilization Method** | Gamma<br>(SAL – $10^{-6}$) | Gamma<br>(SAL – $10^{-6}$) |
| **Single Use, Sterile** | Yes | Yes |
| **Labeling** | Individual IFU: Warning, Cautions, Contraindications, tables, images, organized outline. | Individual IFU: Warning, Cautions, Contraindications, tables, images, organized outline. |
| **Packaging** | Sterile thermal sealed Tyvek/PET Pouch, SBS Carton | Sterile thermal sealed Tyvek/PET Pouch, SBS Carton |
| **Use Environment** | Rx Only – By or on the order of a physician. Hospital, Lab/Surgical Suite | Rx Only – By or on the order of a physician. Hospital, Lab/Surgical Suite |
| **Performance Testing** | ISO 10555-1 Second Edition 2013-07-01. Intravascular catheters -- Sterile, single-use intravascular catheters -- Part 1: General Requirements | ISO 10555-1 Second Edition 2013-07-01. Intravascular catheters -- Sterile, single-use intravascular catheters -- Part 1: General Requirements |

| | | |
|---|---|---|
| **Indications for Use** | 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. | 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. |

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

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

As required by the risk analysis, the following verification tests have been conducted on the XableCath Support Catheter (please refer to Section 17 for additional information):

Direct product bench *in-vitro* comparison testing has shown the subject & predicate products to be 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
- Hemolysis
- Complement Activation
- Platelet and Leukocyte Count
- Sensitization
- Reactivity 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)]**

Twenty-six (26) patients (20 male (77%), 6 female (23%)) whose mean age was 69 years old (range of 55 - 94 years) underwent angiography of the lower extremity through various arterial access sites including femoral, brachial, and radial locations, using 27 XableCath Support Catheters abrasion-tip configuration of various lengths and sizes as part of product design validation (worst-case orientation). Fluoroscopy and angiography were used in each patient to assess the passage adequacy of all XableCath catheters. Each patient was medically observed in follow-up by the same operating physician approximately 6-8 weeks after the PAD interventional procedure.

Within the real-world actual-use assessment, 80 arterial segments were traversed by the XableCath Support Catheter ranging from the radial to the tibial arteries. Within each of the therapeutic vascular deployments, there were no procedural complications attributable to the XableCath Support Catheter. There was one intravascular procedural complication recorded (minor dissection), attributable to post XableCath Support Catheter placement balloon angioplasty, that was uneventfully treated with stent placement. No thrombosis, arterial rupture, or distal embolization occurred in this extended validation assessment. Furthermore, there were no complications noted at a mean follow-up of 53 days post-procedure office visit attributable to the XableCath Support Catheter.

From real-world validation, the following points are concluded from the aforenoted controlled assessment of the XableCath Support Catheter performed on 26 PAD subjects:

- Available sized XableCath Support Catheter abrasion tip configurations raise no new questions of safety and effectiveness, with no intra-procedural complications observed within
- Every arterial access site typically used for lower extremity angiography was used during the assessment;
- Every arterial segment an operator typically passes in lower extremity angiography was safely traversed within the assessment; and
- The XableCath Support Catheter abrasion tip configuration when used in accordance with provided instructions can perform as intended as an over-the-wire PAD catheter for use in exchange of guidewires and other interventional products.

Hence, design & *in-vivo* validation evidence has been firmly established for the subject XableCath Support Catheter product demonstrating both design adequacy and deployment/utilization safety of tip design. The conducted assessment was performed on a real-world validation study cohort (*i.e.,* appropriate demographic group, range of peripheral artery disease, lesion length, calcification range, subject frailty, access site spectrum, traversed vasculature range, and intravascular tissue concerns subject to the full spectrum of therapeutic cautions). As directly identified above, specific attention was paid to vessel perforation, major dissection, or distal debris embolization, of which no XableCath Support Catheter related occurrences were clinically noted, nor were abrasion tip post-procedural clinical sequelae observed. Thus, XableCath Support Catheter tip design (abrasion tip configuration) has been duly confirmed via robust design validation & direct real-world worst-case *in-vivo* application.

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

Based upon unaltered intended use, basal product design, methods of deployment, target population and anatomical site for use, and direct bench comparative assessment the gathered evidence summarized & described within this pre-market notification application demonstrates the XableCath Support Catheter has been shown to be substantially equivalent to the identified 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.