January 21, 2018

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

Re: K183357
Trade/Device Name: XableCath Crossing Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: November 19, 2018
Received: December 4, 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 801and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR

803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Gregory O'Connell 2019.01.21 10:37:48 -05'00'

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)*
K183357

Device Name
XableCath™ Crossing Catheter

Indications for Use *(Describe)*
The XableCath Catheter is intended for use with a guidewire to access discrete regions of the peripheral vasculature. The XableCath™ Crossing Catheter is intended for use to facilitate the intraluminal placement of conventional guidewires beyond stenotic peripheral lesions (including chronic total occlusions) prior to placement of 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.

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510(k) Section 6
510(k) SUMMARY

XableCath Crossing Catheter

Date prepared:	November 03, 2018
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 Crossing Catheter
Common or usual name:	Peripheral Vascular Catheter
Classification name:	Percutaneous Catheter
Classification number:	21 CFRR 870.1250, Procode PDU
Legally marketed device(s) to which equivalence is claimed [21 CFR 807.92(a)(3)]	
eV3/Medtronic Viance Crossing® Catheter (K120533)	
Device description [21 CFR 807.92(a)(4)]	

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

Catalog Number		**Dimensions**	
AbrasionTip (A)	**Blunt Tip (B)**	**Working Length (cm)**	**Recommended Guidewire Inches (mm)**
XC-014-065A	XC-014-065B	65	0.014” (0.36 mm)
XC-014-090A	XC-014-090B	90	0.014” (0.36 mm)
XC-014-145A	XC-014-145B	145	0.014” (0.36 mm)
XC-018-065A	XC-018-065B	65	0.018” (0.46 mm)
XC-018-090A	XC-018-090B	90	0.018” (0.46 mm)
XC-018-145A	XC-018-145B	145	0.018” (0.46 mm)
XC-035-065A	XC-035-065B	65	0.035” (0.89 mm)
XC-035-090A	XC-035-090B	90	0.035” (0.89 mm)

XC-035-145A	XC-035-145B	145	0.035" (0.89 mm)

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 Crossing Catheter strain relief. All provided family member models are compatible with ≥4Fr introducer sheaths. All product configurations are provided sterile, single-use only.

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

The XableCath Catheter is intended for use with a guidewire to access discrete regions of the peripheral vasculature.

The XableCath Crossing Catheter is intended for use to facilitate the intraluminal placement of conventional guidewires beyond stenotic peripheral lesions (including chronic total occlusions) prior to placement of 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 Crossing 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 have an 0.014" product offering possessing similarly offered working lengths, and identical dimensional guidewire compatibility. Additionally, the subject XableCath Crossing Catheter offers additional dimensional working versions as well (*i.e.,* 0.018", and 0.035") within the product family.

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:

Substantial Equivalence Comparison

Product Information	Subject XableCath Crossing Catheter	Predicate Medtronic Viance Crossing® Catheter
510(k) #	K183357 This Submission	K120533
FDA Classification	Class II	Class II
Regulation Number	870.1250	870.1250
Product Code	PDU (projected)	PDU
Indications for Use	The XableCath Catheter is intended for use with a guidewire to access discrete regions of the peripheral vasculature. The XableCath Crossing Catheter is intended for use to facilitate the intraluminal placement of	The Viance Catheter is intended for use with a guidewire to access discrete regions of the peripheral vasculature. When used as part of the Covidien Peripheral System, the Viance Catheter is indicated for use to

		conventional guidewires beyond stenotic peripheral lesions (including chronic total occlusions) prior to placement of other interventional devices.	facilitate the intraluminal placement of conventional guidewires beyond stenotic peripheral lesions (including chronic total occlusions) prior to placement of other interventional devices.
	Proximal Luer/Hub	HDPE	Polycarbonate
	Strain Relief	Olefin	None
	Catheter Shaft	PEBAX/SS braiding/Nylon, Single lumen	PEBAX / SS braiding, Single lumen
	Markers	Cobalt-chromium/SS	SS
	Coating	None	Hydrophilic
	Distal Tip	Atraumatic (Blunt, Abrasion versions)	Atraumatic
	Infusion Pressure/Burst Strength	≥300 psi	≥300 psi
	Outer Diameter	Varies by Model Proximal: 0.043", 0.053", 0.062" Distal: 0.060", 0.070", 0.080" Tip: 0.052", 0.063", 0.071	0.039"
	Guidewire Compatibility	0.014", 0.018", 0.035"	0.014"
	Guide Catheter (max)	≥4Fr	≥6Fr
	Access Sheath (max)	≥4Fr	≥6Fr
	Effective Working Length	65, 90, 145cm	135cm
	Deployment	OTW – Manual	OTW - Manual
	Mechanism of Action	Manual proximal manipulation via axial and torsional applied forces transmitted through catheter length	Manual proximal manipulation via axial and torsional applied forces transmitted through catheter length
	System Design	Proximal Hub/Handle/Luer Catheter Shaft Distal Tip	Proximal Hub/Handle/Luer Catheter Shaft Distal Tip
	Duration of Therapy	Short-term use	Short-term use
	Sterilization Method	Gamma (SAL – 10^{-6})	Gamma (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, clinical outcomes.
	Packaging	Sterile thermal sealed Tyvek/PET Pouch, SBS Carton	Sterile thermal sealed pouch, SBS Carton
	Use Environment	Rx Only – By or on the order of a	Rx Only – By or on the order of a

	physician. Hospital, Lab/Surgical Suite	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 Tensile, Dimensional, Insertion/Withdrawal, Distal Tip, Kink, Torque, Surface Defects, Corrosion, Luer and Hub testing, Radiopacity, Packaging, Biocompatibility ISO 10993	ISO 10555-1 Second Edition 2013-07-01. Intravascular catheters -- Sterile, single-use intravascular catheters -- Part 1: General Requirements (as applicable) Tensile, Dimensional, Insertion/Withdrawal, Distal Tip, Kink, Coating, Torque, Surface Defects, Corrosion, Luer and Hub testing, Radiopacity, Packaging, Biocompatibility ISO 10993

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 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 subject and predicate products are offered in 0.014" workhorse models, whilst the subject product is also offered in 0.018", and 0.035" versions as well.

Despite these noted differences between the subject and predicate products, these attributes are determined to be cumulatively insignificant and do not raise new questions of safety and effectiveness of these products 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 mandated, yet were performed on the subject product to verify actual performance of the device in real-world conditions, secondary to limitations of effective animal modeling for peripheral vascular disease. From real-world assessment, 49 patients underwent lesion modifying therapeutic intravascular treatment with XableCath Catheters for peripheral arterial disease re-canalization. Primary endpoint was successful passage within the target lesion, enabling subsequent therapy (angioplasty and/or stenting), whilst the secondary endpoint was absence of major adverse event attributable to XableCath Catheter product use (perforation, dissection, thrombosis, or distal embolization).

Treatment cohort demographics were 21 females (43%) and 28 males (57%), with a mean age of 71 years (range of 48-94 years). Presenting comorbidities (at least one) within the population was 100%, with Diabetes Mellitus (25 (51%)) being the most common. Peripheral Artery Disease (PAD) classification using the Rutherford Scale (1986, revised 1997) was applied, with Rutherford Class 3-4 in 29 (59%) of the cohort, and Rutherford Class 5-6 in 20 (41%) of the treatment population. The number of lesions treated were 52, associating >100 arterial segments traversed, with treated mean lesion length (cm) of targeted occlusions being 5.6cm. Additionally, vascular lesions treated included Iliac 8 (15%), Femoral – AK Popliteal 36 (68%), BK Popliteal 2 (4%), and Tibial 7 (13%), being those common as PAD therapeutic targets. Lesion characteristics were of an occlusive magnitude that wire and balloon passage was not possible in 15% and 73% of cases respectively, with 54% being Chronic Total Occlusions (CTO) and 81% categorized as moderate/severe calcification.

From these clinical applications, a 98% primary endpoint result was achieved with successful PTA/Stenting & technical success with lesion/claudication crossing. Additionally, 100% secondary endpoint achievement was attained, with routine minor dissection in 10% of treatment subjects, and 2% of subjects experiencing an access site complication - both being successfully treated with standard remedial medical maneuvers, without any residual clinical sequelae at 30 - 45-day post-treatment follow-up (5.6 week average). Of significance, none (0%) of the recorded minor adverse events were either caused by or attributable to the XableCath Crossing Catheter deployment. In addition, human factors engineering and usability assessments were performed to ensure subject product features could be safely and effectively used.

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 Crossing Catheter is shown to be substantially equivalent to the predicate device. Furthermore, the XableCath Crossing 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.