October 15, 2021

BIOTRONIK, Inc.
Jon Brumbaugh
Vice President, Regulatory Affairs and New Product Development
6024 Jean Road
Lake Oswego, Oregon 97035

Re: K212593
Trade/Device Name: ViaCath Catheter; AcQRate Dx Steerable Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe
Regulatory Class: Class II
Product Code: DRF
Dated: August 13, 2021
Received: August 16, 2021

Dear Jon Brumbaugh:

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 801); 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212593

Device Name
ViaCath Catheter
AcQRate Dx Steerable Catheter

Indications for Use *(Describe)*
The catheter is intended for use in diagnostic electrophysiologic procedures in adult patients. These catheters are designed for recording intracardiac electrograms and temporary pacing associated with electrophysiology studies.

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) SUMMARY

VIACATH CATHETERS

510(K) NOTIFICATION K212593

Date Prepared: August 12, 2021

Contact: Jon Brumbaugh
Vice President, Regulatory Affairs & New Product Development
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035 USA
Phone (888) 345-0374
Fax (800) 913-6993
Email: jon.brumbaugh@biotronik.com

Manufacturer: VascoMed GmbH
Hertzallee 1
79589 Binzen, Germany
Phone: +49 (0)7621 16011 0
Fax: +49 (0)7621 16011 9191

Trade Name: ViaCath Catheter

AcQRate Dx Steerable Catheter

Generic/Common Name: Steerable Diagnostic Catheters

Classification Name: Electrode recording catheter or electrode recording probe

Classification & Panel: Class II / 21 CFR § 870.1220, Cardiovascular

Product Code: DRF

Predicate Device: StableMapr Steerable Intracardiac Electrode Catheter (K183547, cleared in July 30, 2019)

Catheter

Device Description [807.92(a)(4)]

The ViaCath* and the AcQRate Dx Steerable Catheters are temporary, steerable, multipolar catheters for sensing of intracardiac signals and diagnostic pacing, in combination with an electrophysiological investigation and recording device.

The main components of the ViaCath catheter are the distal catheter tip with electrodes, catheter shaft, handle, and connecting cable with plug, which is a Redel connector. The ViaCath product family includes the ViaCath and the ViaCath NG models. Multiple electrode configurations are available with various numbers of electrodes, electrode shapes and electrode spacing.

* Unless otherwise noted, the term "ViaCath" is used throughout to represent either ViaCath or AcQRate Dx Steerable Catheter.

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

The indications for use of the catheters are substantially equivalent to that for the predicate.

The catheter is intended for use in diagnostic electrophysiologic procedures in adult patients. These catheters are designed for recording intracardiac electrograms and temporary pacing associated with electrophysiology studies.

Comparison of Technological Characteristics with the Predicate Devices [807.92(a)(6)]

The BIOTRONIK ViaCath Catheters are substantially equivalent to the predicate for this submission, the StableMapr Steerable Intracardiac Electrode Catheter (K183547). These products have the same intended purpose, identical indications for use and have comparable safety and technological features.

The minor device differences do not introduce new issues of safety or effectiveness as demonstrated by the ViaCath Catheter performance testing.

Comparison of Characteristics between Proposed and Predicate Devices			
Characteristics	**Subject Device**	**Predicate Device**	**Rationale for Substantial Equivalence**
	BIOTRONIK ViaCath Catheter (K212593)	**StableMapr™ Steerable Intracardiac Electrode Catheter (K183547)**	
Indications for Use	The catheter is intended for use in diagnostic electrophysiologic procedures in adult patients. These catheters are designed for recording intracardiac electrograms and temporary pacing associated with electrophysiology studies.	The StableMapr™Steerable Intracardiac Electrode Catheters are Intended for use in diagnostic electrophysiologic procedures. Designed for recording intracardiac electrograms and temporary pacing associated with electrophysiology studies.	Substantially equivalent. Minor differences in wording do not raise different questions of safety or effectiveness.
Electrode material	Platinum/iridium	Platinum/iridium	Identical

Comparison of Characteristics between Proposed and Predicate Devices			
Characteristics	**Subject Device**	**Predicate Device**	**Rationale for Substantial Equivalence**
	BIOTRONIK ViaCath Catheter (K212593)	**StableMapr™ Steerable Intracardiac Electrode Catheter (K183547)**	
Size	Outside diameter: 6F (2mm) Length of tip electrode: 2mm Length of ring electrodes: 1mm Effective length ViaCath NG: 110 cm Effective length ViaCath: 90 cm	Outside diameter: 7F Length of tip electrode: 2mm Effective length: 110 cm	Substantially equivalent. Minor differences do not raise different questions of safety or effectiveness.
Poles (Electrodes)	4, 5, 10 or 20 poles	20 poles	Substantially equivalent. Minor differences do not raise different questions of safety or effectiveness.
Curve Shapes	ViaCath NG: 3 curve shapes ViaCath 20: 1 curve shape	Variable curve shapes	Similar design features. Minor differences do not raise different questions of safety or effectiveness.
Connector type	ViaCath NG: 4 pin, 10 pin ViaCath: 10 pin	10 pin	Similar design features. Minor differences do not raise different questions of safety or effectiveness.
Electrode Spacing	ViaCath: 2-8-2 mm ViaCath NG: 2mm, 5mm, 2-6-2mm, 2-8-2mm, 2-10-2mm	2-10-2 mm	Substantially equivalent. The minor difference in electrode spacing does not raise new issues of safety and effectiveness.
Single Use	Yes	Yes	Identical
Supplied Sterile	Yes	Yes	Identical

Performance Data [807.92(b)]

All necessary bench testing was conducted on the ViaCath Catheter to ensure that the device conforms to the design specification and to support a determination of substantial equivalence to the predicate device.

Nonclinical Testing Summary [807.92(b)(1)]

The nonclinical bench testing included:

- Design Verification
    - Dimensional Inspection
    - Visual Inspection
    - Functional and Compatibility Testing
    - Mechanical Testing
    - Corrosion Testing
- Design Validation
    - Usability Testing
- Biocompatibility Testing

In addition, BIOTRONIK has performed sterilization, shelf life and packaging validations. The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the ViaCath Catheters meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the ViaCath Catheters do not introduce new issues of safety or effectiveness when compared to the predicate device.

Test performed	Device	Test method summary	Results
Dimensional and Visual Inspection	ViaCath	Testing demonstrate that requirements of EN ISO 10555-1 have been met and correspond to the defined specifications.	pass
Functional and Compatibility Testing	ViaCath	Functional and compatibility testing was performed with FDA approved external generators. The results of the leakage currents testing revealed an outcome below the limits given in the standard IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012.	pass
Electrical and Mechanical Testing	ViaCath	Testing demonstrates that applicable requirements of EN ISO 10555-1, EN 62366-1 and En ISO 60601-1 have been met to ensure that the catheter is safe.	pass
Shelf life	ViaCath	Confirmation of device functional performance and sterile barrier pouch integrity (seal strength per ASTM F88 and bubble per ASTM F2096) with accelerated aging and simulated distribution per ASTM 4169-16.	pass
Packaging	ViaCath	The methods applied to evaluate the sterile barrier package integrity included transport simulation, preconditioning, seal strength, peel and bubble testing.	pass

Test performed	Device	Test method summary	Results
Biocompatibility	ViaCath	The biocompatibility testing demonstrates that the requirements of ISO 10993 "Biological evaluation of medical devices – Part 1: "Evaluation and testing within a risk management process" and the 2020 FDA Biocompatibility guidance 2have been met.	pass
Sterilization Validation	ViaCath	Full Revalidation of Sterilization Process Performance Qualification ISO 11135:2014 Sterilization of health care products - Ethylene oxide: Requirements of development, validation and routine control of a sterilization process for medical devices.	pass

Clinical Performance Data [807.92(b)(2)]

No clinical performance data was submitted or relied upon in support of the substantial equivalence determination.

Cable

Device description:

BIOTRONIK's MPK-4-R and MPK-10 patient cables are four or ten channel cables to connect electrophysiological diagnostic catheters distributed by BIOTRONIK (e.g. MultiCath, ViaCath) and Acutus Medical (AcQRate Dx Fixed Curve Catheter, AcQRate Dx Steerable Catheter) with electrophysiological examination units and stimulators.

Intended use:

MPK-4-R and MPK-10-R are used to connect BIOTRONIK and Acutus Medical diagnostic catheters to a cardiac stimulator or a lab monitoring system for intracardiac diagnostics as part of an electrophysiological study. MPK-R and diagnostic catheters may only be used by medical personnel qualified to work with lab monitoring systems. Patient cables may not be physically modified, e.g., be shortened.

Cables Functional and Safety Testing:

Test performed	Device	Test method summary	Results
Functional testing: visual inspection, dimensional verification, electrical continuity and resistance, mechanical characteristics	MPK	For validation of the product properties after real time aging of 25 months following tests are performed: a) Visual inspection of the packaging and product b) Functional test of the product c) Electrical measurement	a) Pass b) Pass c) Pass
Sterilization Validation	MPK	Full Revalidation of Sterilization Process Performance Qualification ISO 11135:2014 Sterilization of health care products - Ethylene oxide: Requirements of development,validation and routine control of a sterilization process for medical devices.	Pass
Reprocessing Validation	MPK	Testing demonstrates that the cable can be reprocessed up to 50 times.	Pass

Conclusions [807.92(b)(3)]

Based on the performance testing and the technological characteristics, it can be concluded that the ViaCath Catheter meets its established performance for its intended use and is substantially equivalent to the predicate device.