September 24, 2021

Cardiovascular Systems, Inc.
℅ Jonathan Holmes
Regulatory Affairs Manager
Biomerics
6030 W. Harold Gatty Dr.
Salt Lake City, Utah 84116

Re: K212725
Trade/Device Name: ViperCross Support Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: August 26, 2021
Received: August 27, 2021

Dear Jonathan Holmes:

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,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
Date: 2021.09.24 17:29:17 -04'00'

Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K212725

Device Name
ViperCross™ Support Catheters

Indications for Use *(Describe)*
The ViperCross™ Support Catheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and to sub-selectively infuse / deliver diagnostic and therapeutic agents.

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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510(k) K212725

Submitter:
Cardiovascular Systems, Inc.
1225 Old Highway 8 NW
Saint Paul, MN 55112

Correspondent:
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Salt Lake City, UT 84116
Phone: (801) 503-9065
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Manufacturer:
Cardiovascular Systems, Inc.
1225 Old Highway 8 NW
Saint Paul, MN 55112

DATE PREPARED: 26 August 2021

NAME OF MEDICAL DEVICE:

Proprietary Name:	ViperCross™ Support Catheters
Common/Usual Name:	Percutaneous Catheter
Classification Name:	Catheter, Percutaneous

DEVICE CLASSIFICATION:

Classification Panel:	Cardiovascular
Regulatory Class:	2
Product Code:	DQY
Regulation Number:	21 CFR 870.1250

PREDICATE DEVICE:

Proprietary Name:	ViperCross™ Support Catheters
Common/Usual Name:	Percutaneous Catheter
Classification Name:	Catheter, Percutaneous
510(k) Number:	K211240

DEVICE DESCRIPTION:

The ViperCross™ Support Catheters are single lumen catheters designed for use in the peripheral vasculature. The ViperCross™ Support Catheters provide guidewire support during interventional procedures and allows for the exchange of one distally located guidewire for another while maintaining access to distal vasculature. The ViperCross support catheters have a hydrophilic coating on the distal 30cm, 40cm, 70cm, or 90cm dependent on model length to enhance deliverability to the target vasculature.

The ViperCross™ Support Catheters have three (3) radiopaque marker bands located 0.040" / 1.01mm, 1.968" / 50mm, and 3.937" / 100mm from the distal tip, respectively. The 135cm and 150cm catheters have white positioning marks located at 100cm and 110cm from the distal tip. The proximal end of the catheter incorporates a strain relief and a luer-lock adapter for flushing.

The 014 or 018 ViperCross™ Support Catheter can be placed through the 035 ViperCross™ Support Catheter for extended reach and pushability.

The ViperCross™ Support Catheters have been sterilized with ethylene oxide.

INTENDED USE/INDICATION FOR USE:

Intended Use: The ViperCross™ Support Catheters may be used to facilitate placement and exchange of guidewires and other interventional devices and to selectively infuse/deliver diagnostic and therapeutic agents.

Indications for Use: The ViperCross™ Support Catheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and to sub-selectively infuse/deliver diagnostic and therapeutic agents.

TECNOLOGICAL COMPARISION TO PREDICATE DEVICE:

The ViperCross™ Support Catheter uses the same technology, intended use, fundamental technology and performance as the predicate device (ViperCross™ Support Catheter K211240).

Characteristic	ViperCross™ Support Catheters (Subject Device)	ViperCross™ Support Catheters (K211240 Predicate Device 018 / 035)
Intended Use	The ViperCross™ Support Catheter may be used to facilitate placement and exchange of guidewires and other interventional devices and to	The ViperCross™ Support Catheter may be used to facilitate placement and exchange of guidewires and other interventional devices and to

Characteristic	ViperCross™ Support Catheters (Subject Device)	ViperCross™ Support Catheters (K211240 Predicate Device 018 / 035)
	selectively infuse/deliver diagnostic and therapeutic agents.	selectively infuse/deliver diagnostic and therapeutic agents.
Indications for use	The ViperCross™ Support Catheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and to sub-selectively infuse/deliver diagnostic and therapeutic agents.	The ViperCross™ Support Catheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and to sub-selectively infuse/deliver diagnostic and therapeutic agents.
Dimensions	**Max. Guidewire Diameter:** 018: 0.018" / 0.46mm 035 Straight & Angled: 0.035" / 0.89mm **Working Length:** 018: 65cm, 90cm, & 150cm 035 Straight & Angled: 65cm & 150cm **Distal Tip OD:** 018: 0.025" / 0.63mm 035 Straight & Angled: 0.45" / 1.14mm **Proximal Shaft OD:** 018: 0.0375" / 0.95mm 035 Straight & Angled: 0.056" / 1.42mm **Min Guide Catheter ID:** 018: 0.042" / 1.07mm 035 Straight & Angled: 0.061" / 1.55mm	**Max. Guidewire Diameter:** 018: 0.018" / 0.46mm 035 Straight & Angled: 0.035" / 0.89mm **Working Length:** 018: 135cm 035 Straight & Angled: 90cm & 135cm **Distal Tip OD:** 018: 0.025" / 0.63mm 035 Straight & Angled: 0.45" / 1.14mm **Proximal Shaft OD:** 018: 0.0375" / 0.95mm 035 Straight & Angled: 0.056" / 1.42mm **Min Guide Catheter ID:** 018: 0.042" / 1.07mm 035 Straight & Angled: 0.061" / 1.55mm

Characteristic	ViperCross™ Support Catheters (Subject Device)	ViperCross™ Support Catheters (K211240 Predicate Device 018 / 035)
Distal Tip Angulation	**018:** N/A **035 Straight:** N/A **035 Angled:** 30°	**018:** N/A **035 Straight:** N/A **035 Angled:** 30°
Angled Tip Length	**018:** N/A **035 Straight:** N/A **035 Angled:** 1.2cm	**018:** N/A **035 Straight:** N/A **035 Angled:** 1.2cm
Shaft Construction	Coiled	Coiled
Packaging	Mylar / Tyvek Pouch	Mylar / Tyvek Pouch
Sterilization	Ethylene Oxide	Ethylene Oxide

The ViperCross™ Support Catheter is substantially equivalent to the predicate device, ViperCross Support Catheter (K211240).

PERFORMANCE TESTING

The ViperCross™ Support Catheter was thoroughly tested and verifies that it performs as designed and is suitable for it intended use.

Performance Testing included the following:

- Working length
- Overall length
- Distal shaft outer diameter
- Proximal shaft outer diameter
- Inner diameter
- Contrast injection
- Leak test air aspiration
- Liquid leak resistance
- High pressure leak test
- Surface finish
- Particulate
- Trackability / simulated use
- Hydrophilic Coating
- Torque transmission
- Kink resistance

- Tip flexibility
- Tensile strength
- 035 only – Tip Angle

All testing met the requirements and passed. There are no new questions raised regarding safety or efficacy of the ViperCross™ Support Catheter.

CONCLUSION:

The ViperCross™ Support Catheter is identical in general design, materials, sterilization, principles of operation, performance, intended use and indications for use to the cited predicate.