August 26, 2021

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

Re: K211240
Trade/Device Name: ViperCross Support Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 28, 2021
Received: July 29, 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,

for 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)*
K211240

Device Name
ViperCross™ Support Catheters

Indications for Use *(Describe)*

0.014"

The ViperCross™ Support Catheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the peripheral and/or coronary 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.

0.018" & 0.035"

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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CARDIOVASCULAR SYSTEMS, INC.

1225 Old Highway 8 NW
Saint Paul, MN 55112

510(k) K211240

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

Correspondent:
Jonathan Holmes
6030 W Harold Gatty Dr.
Salt Lake City, UT 84116
Phone: (801) 503-9065
Email: jholmes@biomerics.com

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

DATE PREPARED: 22 April 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 1 (014):

Proprietary Name:	SuperCross Microcatheter
Common/Usual Name:	Percutaneous Catheter
Classification Name:	Catheter, Percutaneous
510(k) Number:	K101659

PREDICATE DEVICE 2 (018 & 035):

Proprietary Name:	Quick-Cross Extreme & Quick-Cross Select
Common/Usual Name:	Percutaneous Catheter
Classification Name:	Catheter, Percutaneous
510(k) Number:	K082561

DEVICE DESCRIPTION:

014: The ViperCross™ Support Catheter is a single lumen catheter designed for use in the peripheral and/or coronary vasculature. The ViperCross™ Support Catheter provides 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 90cm or 70cm dependent on model length to enhance deliverability to the target vasculature.

The ViperCross™ Support Catheters have a single radiopaque marker band located 0.040" / 1.02mm from the distal tip. The 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.

018/035: The ViperCross™ Support Catheter is a single lumen catheter designed for use in the peripheral vasculature. The ViperCross™ Support Catheter provides 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 90cm, 70cm, or 40cm dependent on model length to enhance deliverability to the target vasculature.

The ViperCross™ Support Catheters have a single radiopaque marker band located 0.040" / 1.02mm from the distal tip. The 135cm 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 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.

014 Indications for Use: The ViperCross™ Support Catheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the peripheral and/or coronary 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.

018/035 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:

Technologically the ViperCross™ Support Catheter is substantially equivalent to the SuperCross Microcatheter, (K101659) and Quick-Cross Extreme & Quick-Cross Select, (K082561) in terms of design, materials, technology and performance.

The ViperCross™ Support Catheter uses the same technology and has a similar intended use, fundamental technology and performance as the predicate device.

Characteristic	ViperCross™ Support Catheters (Subject Device)	SuperCross™ Microcatheter (Predicate for 014 Straight Model)	Quick-Cross Extreme & Quick-Cross Select (Predicate for 018 Straight & 035 Straight/Angled Models)
Intended Use	The ViperCross™ Support Catheter may be used to facilitate placement and exchange of guidewires and other interventional devices and to selectively infuse/deliver diagnostic and therapeutic agents.	The SuperCross Microcatheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary and/or peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and to subselectively infuse/deliver diagnostic and therapeutic agents.	Quick-Cross Extreme and Quick-Cross Select support catheters are intended to guide and support a guidewire during access of the coronary or peripheral vasculature, allow for wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.
Indications for use	**014** The ViperCross™ Support Catheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the peripheral and/or coronary vasculature. It may be used to facilitate placement and exchange of guidewires and other	The SuperCross Microcatheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary and/or peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional	Quick-Cross Extreme and Quick-Cross Select support catheters are intended to guide and support a guidewire during access of the coronary or peripheral vasculature, allow for wire exchanges and provide a conduit for the delivery of saline

Characteristic	ViperCross™ Support Catheters (Subject Device)	SuperCross™ Microcatheter (Predicate for 014 Straight Model)	Quick-Cross Extreme & Quick-Cross Select (Predicate for 018 Straight & 035 Straight/Angled Models)
	interventional devices and to sub-selectively infuse/deliver diagnostic and therapeutic agents. **018/035** 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.	devices and to subselectively infuse/deliver diagnostic and therapeutic agents.	solutions or diagnostic contrast agents.
Technology			
Dimensions	**Max. Guidewire Diameter:** 014: 0.014" / 0.36mm 018: 0.018" / 0.46mm 035 Straight & Angled: 0.035" / 0.89mm **Working Length:** 014: 135cm & 150cm 018: 135cm 035 Straight & Angled: 90cm & 135cm	**Max. Guidewire Diameter:** 0.014" / 0.36mm **Working Length:** 130cm & 150cm **Distal Tip OD:** 0.024" / 0.61mm **Proximal Shaft OD:** 0.033" / 0.84mm **Min. Guide Catheter ID:** 0.042" / 1.07mm	**Max. Guidewire Diameter:** Extreme 018: 0.018" / 0.46mm Extreme 035 Straight: 0.035" / 0.89mm Select 035 Angled: 0.035" / 0.89mm **Working Length:** Extreme 018: 135cm Extreme 035 Straight: 90cm & 135cm

Characteristic	ViperCross™ Support Catheters (Subject Device)	SuperCross™ Microcatheter (Predicate for 014 Straight Model)	Quick-Cross Extreme & Quick-Cross Select (Predicate for 018 Straight & 035 Straight/Angled Models)
	Distal Tip OD: 014: 0.021" / 0.53mm 018: 0.025" / 0.63mm 035 Straight & Angled: 0.45" / 1.14mm **Proximal Shaft OD:** 014: 0.375" / 0.95mm 018: 0.0375" / 0.95mm 035 Straight & Angled: 0.056" / 1.42mm **Min Guide Catheter ID:** 014: 0.042" / 1.07mm 018: 0.042" / 1.07mm 035 Straight & Angled: 0.061" / 1.55mm		Select 035 Angled: 90cm & 135cm **Distal Tip OD:** Extreme 018: 0.038" Extreme 035 Straight: 0.052" Select 035 Angled: 0.052" **Proximal Shaft OD:** Extreme 018: 0.044" Extreme 035 Straight: 0.059" Select 035 Angled: 0.059" **Min. Guide Catheter ID:** Extreme 018: 0.049" / 1.24mm Extreme 035 Straight: 0.064" / 1.63mm Select 035 Angled: 0.064" / 1.63mm
Distal Tip Angulation	**014:** N/A **018:** N/A **035 Straight:** N/A **035 Angled:** 30°	N/A	**Extreme 018:** N/A **Extreme 035 Straight:** N/A **Select 035 Angled:** 45°
Angled Tip Length	**014:** N/A **018:** N/A **035 Straight:** N/A	N/A	**Extreme 018:** N/A **Extreme 035 Straight:** N/A

Characteristic	ViperCross™ Support Catheters (Subject Device)	SuperCross™ Microcatheter (Predicate for 014 Straight Model)	Quick-Cross Extreme & Quick-Cross Select (Predicate for 018 Straight & 035 Straight/Angled Models)
	035 Angled: 1.2cm		**Select 035 Angled:** 7mm
Shaft Construction	Coiled	Coiled	Coiled
Packaging	Mylar / Tyvek Pouch	Tyvek Pouch	Tyvek Pouch
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide

The ViperCross™ Support Catheter is substantially equivalent to the predicate device, SuperCross Microcatheter, (K101659) and Quick-Cross Extreme Support Catheter, (K082561). The ViperCross™ Support Catheter, SuperCross Microcatheter, and the Quick-Cross Extreme Support Catheter provide in conjunction with a steerable guidewire, provide access to discrete regions of the coronary and/or peripheral vasculature.

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
- Radiopacity of tip
- Contrast injection
- Leak test air aspiration
- Liquid leak resistance
- High pressure leak test
- Surface finish
- Particulate
- Corrosion resistance
- Trackability / simulated use
- Torque transmission
- Kink resistance
- Tip flexibility

- Tensile strength
- Luer hub fitting
- 035 only – Tip Angle

Biocompatibility per ISO 10993-1 for an external communicating device, limited (<24 hour) blood contacting device.

- ASTM Hemolysis assay
- Heparinized blood platelet and leukocyte count assay
- Partial thromboplastin Time (PTT) assay
- Complement activation assay
- MEM Elution cytotoxicity assay
- Material meditated pyrogenicity test
- Acute systemic toxicity test
- Intracutaneous reactivity test
- Guinea pig maximization test
- In-vitro blood loop assay with comparison article

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 substantially equivalent in design, materials, sterilization, principles of operation, performance and indications for use to the cited predicate.