December 29, 2018

Cardiovascular Systems, Inc.
Erika Huffman
Regulatory Affairs Manager
1225 Old Highway 8 NW
St. Paul, Minnesota 55112

Re: K183000
Trade/Device Name: ViperCath XC Peripheral Exchange Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: October 29, 2018
Received: October 30, 2018

Dear Erika Huffman:

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/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,

Michael John -S
2018.12.29 19:57:01 -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)*
K183000

Device Name
ViperCath XC Exchange Catheter, 035-XC-200-0; ViperCath XC Exchange Catheter, 035-XC-200-1

Indications for Use *(Describe)*
The ViperCath XC Peripheral Exchange Catheter is intended to guide and support a guide wire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline or diagnostic contrast 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.

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

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510(k) Summary / Statement

Submitter:	Cardiovascular Systems, Inc. 1225 Old Highway 8 NW Saint Paul, MN 55112
Contact Person:	Erika Huffman, MS, RAC Regulatory Affairs Manager Cardiovascular Systems, Inc. 1225 Old Highway 8 NW St. Paul, MN 55112 Ph: 651-259-1608 ehuffman@csi360.com
Date Prepared:	October 30, 2018
Trade Name:	ViperCath™ XC Peripheral Exchange Catheter
Common Name:	Percutaneous Catheter, 21 CFR 870.1250
Classification:	Class II
Product Code:	DQY
Predicate Device(s):	K110540 - NaviCross™ Support Catheter
Device Description:	The ViperCath XC Exchange Catheter (ViperCath XC) is intended to be used to facilitate vascular access and guidewire exchanges during peripheral vascular intervention procedures. It is provided in a 200 cm length, to facilitate the radial access approach, with either a straight or angled tip. There are no accessories for this device. The catheter shaft has radiopaque marker bands at distances of 1 cm and 5 cm from the distal tip. Two additional printed markers are located 120 cm and 150 cm from the distal tip and are provided to aid with placement.
Intended Use:	The ViperCath™ XC Peripheral Exchange Catheter is intended to guide and support a guide wire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline or diagnostic contrast agents.

Comparison to Predicate:

	ViperCath™ XC Peripheral Exchange Catheter (subject device)	Terumo NaviCross™ Support Catheter (predicate device)
Effective Length(s)	200 cm	65, 90, 135, 150 cm
Recommended Guide Catheter	5 Fr	4 Fr
Shaft Design	Braid-reinforced	Braid-reinforced
Tip Shape	Straight, Angled	Straight, Angled
Maximum Injection Pressure	600 psi	750 psi
Guidewire Compatibility	0.035”	0.035”
Hydrophilic Coating	No	Yes
Sterile	Yes	Yes
Single Use	Yes	Yes

Functional and Safety Testing:

Testing was performed in accordance with applicable standards and guidance, including *FDA Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters* (September 2010).

<u>Biocompatibility Testing:</u>

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity
- Acute Systemic Toxicity
- Hemocompatibility
- Thrombogenicity
- Pyrogenicity

<u>Bench Testing</u>

- Dimensional verification – luer, shaft, tip
- Bond strengths
- Tracking
- Guidewire Exchange
- Radiopacity
- Wrap/Kink
- Torque Transfer
- Torque to Failure
- Fluid flow
- Burst Pressure
- Leakage
- Usability/Human Factors

Conclusion:	The ViperCath XC Exchange Catheter data supports that no new questions of safety or effectiveness were identified compared to the predicate device.