May 26, 2021

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

Re: K211251
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: April 23, 2021
Received: April 26, 2021

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/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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211251

Device Name
ViperCath™ XC Peripheral Exchange Catheter

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

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:	April 23, 2021
Trade Name:	ViperCath™ XC Peripheral Exchange Catheter
Common Name:	Percutaneous Catheter, 21 CFR 870.1250
Classification:	Class II
Product Code:	DQY
Predicate Device:	ViperCath XC Peripheral Exchange Catheter - K183000
Device Description:	The ViperCath XC Exchange Catheter is intended to be used to facilitate vascular access and guidewire exchanges during peripheral vascular intervention procedures. It is available in the following lengths with a straight tip: 65, 90, 135, and 150 cm as described in this submission. A 200 cm length is also available and was previously cleared under K183000 with a straight tip and an angled tip. There are no accessories for this device. The catheter is compatible with .035" guidewires and has radiopaque marker bands at distances of 1 cm and 5 cm from the distal tip. The ViperCath XC is supplied sterile with one catheter per box.
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)**	**ViperCath™ XC Peripheral Exchange Catheter K183000 (Predicate Device)**
	Effective Length(s)	65, 90, 135, 150 cm	200 cm
	Recommended Guide Catheter	5 Fr	5 Fr
	Shaft Design	Braid-reinforced	Braid-reinforced
	Tip Shape	Straight	Straight, Angled
	Maximum Injection Pressure	600 psi	600 psi
	Guidewire Compatibility	0.035”	0.035”
	Hydrophilic Coating	No	No
	Sterile	Yes	Yes
	Single Use	Yes	Yes
Functional and Safety Testing:	Dimensional checks and torque to failure testing were performed to verify the modifications are acceptable and meet specifications over the life of the device.		
Conclusion:	The ViperCath XC Exchange Catheter (femoral lengths) is substantially equivalent to the predicate device and the modifications do not introduce new questions of safety or effectiveness.		