March 18, 2020

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

Re: K200198
Trade/Device Name: WIRION™
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: January 24, 2020
Received: January 27, 2020

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,

Finn Donaldson
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)*
K200198

Device Name
WIRION™

Indications for Use *(Describe)*
The WIRION™ is indicated for use as an embolic protection system to contain and remove embolic material (thrombus/ debris) while performing atherectomy in calcified lesions of the lower extremities. The diameter of the vessel at the site of filter basket placement should be between 3.5mm to 6.0mm. WIRION™ may be used with commercially available 0.014" guide wires.

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

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:	January 24, 2020
Trade Name:	WIRION™
Common Name:	Embolic Protection System
Regulation Number:	870.1250, Percutaneous Catheter
Classification:	Class II
Product Code:	NTE
Predicate Device(s):	K180023 – WIRION™ (Gardia Medical Ltd.)
Device Description:	WIRION™ is a temporary Embolic Protection System (EPS), filtering distal to the intervention site. The system is a rapid exchange, pre-crimped filter that can be used with any commercially available 0.014" guide wires.
Indications for Use:	The WIRION™ is indicated for use as an embolic protection system to contain and remove embolic material (thrombus/debris) while performing atherectomy in calcified lesions of the lower extremities. The diameter of the vessel at the site of filter basket placement should be between 3.5mm to 6.0mm. WIRION™ may be used with commercially available 0.014" guide wires.
Comparison to Predicate Device:	The proposed device is identical to the predicate device.
Functional and Safety Testing:	No new functional or safety testing was conducted or deemed necessary since the device is identical to the predicate device.
Conclusion:	No new questions of safety or effectiveness were identified compared to the predicate device and the device should perform as intended under the specified use conditions.