April 17, 2018

Cardiovascular Systems, Inc.
Ms. Susan Wolf
Regulatory Affairs Manager
1225 Old Highway 8 NW
Saint Paul, Minnesota 55112

Re: K180416
Trade/Device Name: ViperWire Advance Flex Tip Peripheral Guide Wire
(OAS component of: Diamondback 360 Peripheral Orbital Atherectomy System and Stealth 360 PAD System)
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: February 14, 2018
Received: February 15, 2018

Dear Ms. Wolf:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

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)*
K180416

Device Name
ViperWire Advance Flex Tip Peripheral Guide Wire
(OAS component of: Diamondback 360 Peripheral Orbital Atherectomy System and Stealth 360 PAD System)

Indications for Use *(Describe)*
The Stealth 360 Orbital PAD System and the Diamondback 360 Peripheral Orbital Atherectomy System are percutaneous orbital atherectomy systems indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and who are acceptable candidates for percutaneous transluminal atherectomy.

The OAS supports removal of stenotic material from artificial arteriovenous dialysis fistulae (AV shunt). The OAS is a percutaneous orbital atherectomy system indicated as a therapy in patients with occluded hemodialysis grafts who are acceptable candidates for percutaneous transluminal angioplasty.

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.

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CARDIOVASCULAR SYSTEMS, INC.

510(K) SUMMARY

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

Contact: Susan Wolf, RAC
Phone: (651) 202-4149
Fax: (612) 259-2094

Summary Date: April 16, 2018

Trade Name: ViperWire Advance Flex Tip Peripheral Guide Wire
(OAS component of: Diamondback 360® Peripheral Orbital Atherectomy System and Stealth 360® PAD System)

Product Code: MCW—Catheter, Peripheral, Atherectomy
Classification Regulation: 21 CFR 870.4875—Intraluminal Artery
Stripper Classification: II
Primary Predicate:

510(k) Number:	K151260
Manufacturer:	Cardiovascular Systems, Inc.
Trade Name:	Stealth 360® PAD System and Diamondback 360® Peripheral Orbital Atherectomy System

Additional Reference Predicate:

510(k) Number:	K170792
Manufacturer:	Cardiovascular Systems, Inc.
Trade Name:	Diamondback 360® Peripheral Orbital Atherectomy System

Description of Device

The atherectomy guide wire is a component that is part of the Stealth 360 Orbital PAD System and Diamondback 360 Peripheral Orbital Atherectomy System. The Stealth 360 Orbital PAD System and the Diamondback 360 Peripheral Orbital Atherectomy System (OAS) are intended for use in the treatment of peripheral arteries and A-V graft (shunt) stenosis.

The OAS provides a method of removing stenotic material from peripheral arteries and A-V grafts. The Stealth 360 and the Diamondback 360 use an eccentrically rotating sanding surface (crown) to remove stenotic material on the vessel wall. The stenotic particles that are removed are small enough to be absorbed by the body. In addition to the atherectomy guide wire, the

Stealth 360® Orbital PAD System and the Diamondback 360® Peripheral Orbital Atherectomy System consists of the following components: Orbital Atherectomy Device (OAD), Saline Infusion Pump, and Atherectomy Lubricant (e.g., ViperSlide).

Description of Change

Guide wire component modification and additional guidewire lengths and updates to the OAS pump to comply with IEC 60601-1-2:2014 (4th edition).

Indications For Use

The Stealth 360® Orbital PAD System and the Diamondback 360® Peripheral Orbital Atherectomy System are percutaneous orbital atherectomy systems indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and who are acceptable candidates for percutaneous transluminal atherectomy. The OAS supports removal of stenotic material from artificial arteriovenous dialysis fistulae (AV shunt). The OAS is a percutaneous orbital atherectomy system indicated as a therapy in patients with occluded hemodialysis grafts who are acceptable candidates for percutaneous transluminal angioplasty.

Technology

The Stealth 360® Orbital PAD System and the Diamondback 360® Peripheral Orbital Atherectomy System provide a method of removing or reducing occlusive atherosclerotic or stenotic material. The OAS applies a diamond coated, eccentrically rotating sanding surface to remove stenotic material on the vessel wall. The stenotic particles that are removed are small enough to be absorbed by the body. The ViperWire Advance FlexTip Guide Wire is a smooth, stainless steel wire, with a silicone coating, and a radiopaque distal spring tip. The guide wire allows for proper positioning of the device crown within peripheral arteries and provides a center of rotation for the device drive shaft. These extended length guide wires use the same technology as the previously cleared Stealth 360® Orbital PAD.

Specifications

VIPERWIRE ADVANCE Guide Wire Specifications				
			VPR-GW-ELFT14	**VPR-GW-ELFT18**
Guidewire Length	335 cm	335 cm	475 cm	475 cm
Guidewire Coating	Silicone	Silicone	Silicone	Silicone
Core wire diameter	.014”	.014”	.014”	.014”
Core wire material	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel
Spring Tip Length	3 cm	3 cm	3 cm	3 cm
Spring Tip Diameter	.014”	.018”	.014”	.018”
Spring Tip Material	Platinum/ Tungsten	Platinum/ Tungsten	Platinum/ Tungsten	Platinum/ Tungsten
Spring Tip Shape	Straight	Straight	Straight	Straight

Performance Data

The ViperWire Advance FlexTip Guide Wire was evaluated using the following performance bench testing to confirm the performance characteristics as compared to the predicate device.

- Manual Track Testing
- Torque Transfer Testing
- Torque Strength Testing
- Life Testing
- Orbit Testing
- Tensile Testing ISO 11070
- Tip Flexibility Testing
- Transfer Force Test
- ISO Corrosion, Flex, and Fracture Test ISO 11070
- Particulate USP <788>
- Biocompatibility ISO 10993
- OAS Flow Tests
- OAS Pump Functional Tests
- IEC 60601-1-2:2014 (4th edition)

All test results demonstrate that the materials chosen, the manufacturing processes, and the design utilized for the ViperWire Advance FlexTip Guide Wire and OAS pump met the established specifications necessary for consistent performance during its intended use.

Conclusion

The ViperWire Advance Flex Tip Guide Wire and OAS pump met all predetermined acceptance criteria of design verification and validation testing as specified by applicable standards, test protocols, and/or customer inputs. Testing results demonstrate that the ViperWire AdvanceFlex Tip Guide Wire and OAS pump used with the Stealth 360® Orbital PAD System and Diamondback 360® Peripheral Orbital Atherectomy System is substantially equivalent to the legally marketed predicate device, does not raise any new safety or effectiveness questions, and performs as well as the predicate device.