December 13, 2018

Cardiovascular Systems Inc.
Kris Miller
Sr. Regulatory Specialist
1225 Old Highway 8 NW
St. Paul, Minnesota 55112

Re: K182397
Trade/Device Name: Diamondback 360 Peripheral Orbital Atherectomy System Exchangeable Series
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: November 6, 2018
Received: November 7, 2018

Dear Ms. Miller:

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,

Gregory O'Connell
2018.12.13 14:39:01 -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)*
K182397

Device Name
Diamondback 360 Peripheral Orbital Atherectomy System Exchangeable Series

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

The Exchangeable Series OAS supports removal of stenotic material from artificial arteriovenous dialysis fistulae (AV shunt). The system 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary / Statement

510k Number	K182397
Submitter:	Cardiovascular Systems Inc. 1225 Old Highway 8 NW St. Paul, MN 55112
Contact Person:	Kris Miller Sr. Regulatory Affairs Specialist Cardiovascular Systems Inc. 1225 Old Highway 8 NW St. Paul, MN 55112 USA Phone: 651-259-1656 Fax: 651-259-2094 kmiller@csi360.com
Date Prepared:	August 31, 2018
Trade Name:	Diamondback 360® Peripheral Orbital Atherectomy System Exchangeable Series
Common Name:	Intraluminal Artery Stripper
Classification:	Class II, 21 CFR 870.4875
Product Code:	MCW
Predicate Device:	K152694 - Diamondback 360® Peripheral Orbital Atherectomy System (Cardiovascular Systems, Inc.)
Device Description:	The DIAMONDBACK 360 Peripheral Orbital Atherectomy System (OAS) Exchangeable Series is designed to remove or reduce occlusive material and restore luminal patency by using an orbiting, diamond-coated, eccentrically mounted crown. The DIAMONDBACK 360 Peripheral Orbital Atherectomy System Exchangeable Series consists of the following main components: 1. Reusable Saline Pump (provided non-sterile) 2. Single-use Orbital Atherectomy Device (OAD) (provided sterile). The Exchangeable Series OAD consists of a physician-operated handle and an interchangeable crown cartridge. 3. Single-use Atherectomy lubricant (provided sterile) 4. Single-use Atherectomy guide wire (provided sterile) Mechanism of Action

	The Exchangeable Series mechanism of action is identical to the predicate device and defined by: • Centrifugal force • Orbital rotation • Differential sanding • Bi-directional sanding The rapidly rotating eccentric crown creates a centrifugal force that presses the diamond-coated crown against the calcified plaque. With each pass of the crown, plaque is reduced and the diameter of the orbit increases.
Indications for Use:	The Diamondback 360 Peripheral Orbital Atherectomy System Exchangeable Series is a percutaneous orbital atherectomy system indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and who are acceptable candidates for percutaneous transluminal atherectomy. The Exchangeable Series OAS supports removal of stenotic material from artificial arteriovenous dialysis fistulae (AV shunt). The system is a percutaneous orbital atherectomy system indicated as a therapy in patients with occluded hemodialysis grafts who are acceptable candidates for percutaneous transluminal angioplasty.
Comparison with Predicate Device:	The Exchangeable Series OAS has the same intended use, mechanism of action and indications for use as the predicate device. All Exchangeable OADs use the same base handle to which a crown cartridge is attached. The only differences between the various crown cartridges are the length of the drive shaft and the size and style of the crown on each model. With the Exchangeable Series OAS, up to 3 crowns can be used with a single handle. An additional length of drive shaft has been added to the DIAMONDBACK 360 Peripheral Orbital Atherectomy System (OAS) Exchangeable Series. The 75cm drive shaft materials and construction are identical to the currently cleared CSI drive shaft devices.

	There has been a change in materials that are in the indirect patient contact pathway. These new components are located inside the cartridge housing.

Performance Data:	<u>Biocompatibility Testing</u>
	The biocompatibility evaluation for the Exchangeable OAD device included the following tests:
	• Cytotoxicity
	• Sensitization
	• Irritation/Intracutaneous Reactivity
	• Systemic Toxicity
	• Pyrogenicity
	• Hemolysis Study
	
	<u>Performance/Bench Testing</u>
	The following bench tests on the Diamondback 360 Peripheral Orbital Atherectomy System Exchangeable Series were conducted in accordance with applicable standards and guidance.
	• Track Verification Testing
	• Stall / Life and Tight Stenosis Verification Testing
	• Device Pre-Conditioning Verification Testing
	• Handle Potting and Switch Mount Base and Process Updates
	• Handle Life Verification Testing
	• Tensile Verification Testing
	• Temperature and Saline Flow Life Verification Testing
	• Dimensional and Weight Verification Testing
	• Glide Start Up Life Verification Testing
	• Orbit Characterization Testing
	• Switch Logic Verification Testing
	• Miscellaneous Verification Testing: Includes the following tests:
	  ○ Traverse Force
	  ○ Knob Lock Force
	  ○ Exchange Durability
	  ○ Guidewire Back Loading
	• Usability/human factors Testing
	
	These tests performed are intended to verify that the design meets all product specifications and address the potential safety hazards that have been identified.

Conclusion:	The data provided supports no new questions of safety or effectiveness of the Diamondback 360 Peripheral Orbital Atherectomy System Exchangeable Series compared to the predicate device. The mechanical testing results demonstrate that the device should perform as intended in the specified use conditions.