November 19, 2020

Cardiovascular Systems Inc.
Nikita Basandra
Principal Regulatory Affairs Specialist
1225 Old Highway 8 NW
Saint Paul, Minnesota 55112

Re: K203008
Trade/Device Name: DIAMONDBACK 360 Peripheral Orbital Atherectomy System, DIAMONDBACK 360 Peripheral Orbital Atherectomy System, Exchangeable Series, Stealth 360 Peripheral Orbital Atherectomy System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: September 30, 2020
Received: October 7, 2020

Dear Nikita Basandra:

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,

Gregory O'Connell
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)*
K203008

Device Name
Diamondback 360® Peripheral Orbital Atherectomy System
Diamondback 360® Peripheral Orbital Atherectomy System, Exchangeable Series
Stealth 360® Peripheral Orbital Atherectomy System

Indications for Use *(Describe)*
The Diamondback 360® Peripheral Orbital Atherectomy System 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 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.

The Stealth 360® Peripheral Orbital Atherectomy System 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 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.

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

Submitter:	Cardiovascular Systems, Inc. 1225 Old Highway 8 NW Saint Paul, MN 55112
Contact Person:	Nikita Basandra Principal Regulatory Affairs Specialist Cardiovascular Systems, Inc. 1225 Old Highway 8 NW Saint Paul, MN 55112 Ph: 651-259-8206 nbasandra@csi360.com
Date Prepared:	September 30, 2020
Trade Name:	• DIAMONDBACK 360 Peripheral Orbital Atherectomy System • DIAMONDBACK 360 Peripheral Orbital Atherectomy System Exchangeable Series • Stealth 360 Peripheral Orbital Atherectomy System
Common Name:	Intraluminal Artery Stripper
Classification:	Class II, 21 CFR 870.4875
Product Code:	MCW
Predicate Device(s):	• K190634 - DIAMONDBACK 360® and Stealth 360® Peripheral Orbital Atherectomy Systems (Cardiovascular Systems, Inc.) • K182397 - DIAMONDBACK 360® Peripheral Orbital Atherectomy System Exchangeable Series

Device Description:	The DIAMONDBACK 360 Peripheral OAS, Stealth 360 Peripheral OAS, and DIAMONDBACK 360 OAS Exchangeable Series are designed to remove or reduce occlusive material and restore luminal patency by using an orbiting, diamond-coated, eccentrically mounted crown. Each OAS 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) <u>Mechanism of Action</u> The Diamondback, Stealth, and Exchangeable Series OAS mechanism of action is identical to the predicate device and is defined by: • Centrifugal force • Orbital rotation • Differential sanding • Bi-directional sanding The proposed device has the same intended use, mechanism of action, and indications for use as the predicate. The proposed device differs in manufacturing process and supplier of a device component.
Indications for Use:	The Diamondback 360® [Stealth 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 to Predicate:		**DIAMONDBACK 360 Peripheral OAS (Predicate Device)**	**DIAMONDBACK 360 Peripheral OAS, Stealth 360 Peripheral OAS, and DIAMONDBACK 360 OAS Exchangeable Series (Subject Device)**
	Indications for Use	The OAS 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 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.	Same
	Crown Styles	Solid Classic Micro	Same
	Crown Sizes (mm)	1.25 1.50 1.75 2.00	Same
	OAD driveshaft lengths (cm)	75 145 180 200	Same
	Sterile	Yes	Same
	Single Use	Yes	Same
	Principles of Operation	Same	Same
	Used in conjunction with • **OAS Pump** • **CSI Peripheral Guide Wires** • **ViperSlide Lubricant**	Yes	Same

Performance Data:	Biocompatibility Testing The biocompatibility evaluation for the DIAMONDBACK 360 Peripheral OAS, Stealth 360 Peripheral OAS, and DIAMONDBACK 360 OAS Exchangeable Series included the following tests: • Cytotoxicity • Sensitization • Irritation/Intracutaneous Reactivity • Systemic Toxicity • Pyrogenicity • Hemolysis Study • Complement Activation Assay • Platelet and Leukocyte Counts • Partial Thromboplastin Time Bench Testing The following bench tests were conducted in accordance with applicable standards and guidance. • Corrosion Resistance Testing • Orbit Characterization Testing • Particulate Testing • Radiopacity Assessment • Tensile Verification 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 for the DIAMONDBACK 360 Peripheral Orbital Atherectomy System, the Stealth 360 Peripheral Orbital Atherectomy System, and the DIAMONDBACK 360 Peripheral Orbital Atherectomy System Exchangeable Series compared to the predicate device. The testing results demonstrate that the devices should perform as intended under the specified use conditions.