March 1, 2022

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

Re: K220109
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: January 12, 2022
Received: January 13, 2022

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)*
K220109

Device Name
Diamondback 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.

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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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:

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

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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)*
K220109

Device Name
Stealth 360® Peripheral Orbital Atherectomy System

Indications for Use *(Describe)*
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.

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)

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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)*
K220109

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)

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1 510(K) SUMMARY (K220109)

Submitter:	Cardiovascular Systems, Inc. 1225 Old Highway 8 NW Saint Paul, MN 55112
Contact Person:	Nikita Basandra Regulatory Affairs Manager Cardiovascular Systems, Inc. 1225 Old Highway 8 NW Saint Paul, MN 55112 Ph: 651-259-8206 nbasandra@csi360.com
Date Prepared:	January 20, 2022
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
Regulation Number:	21 CFR 870.4875
Classification:	Class II
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 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.
Intended Use:	<u>The Diamondback 360® Peripheral Orbital Atherectomy System</u> 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. <u>Stealth 360® Peripheral Orbital Atherectomy System</u> 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. <u>Diamondback 360® Peripheral Orbital Atherectomy System Exchangeable Series</u> 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 to Predicate Device:	The modified Diamondback 360® [Stealth 360®] Peripheral Orbital Atherectomy System [Exchangeable Series] devices are identical to the predicate devices as follows: • Same regulation number, product code and classification • Same intended use and indications for use • Same vessel diameter range and anatomic location of use • Same design and materials • Same hardware • Same principles of operation • Same sterilization method and SAL • Same number of uses per device (single use) • Same performance specifications The modified devices are different from the predicate device in that the software has been updated to include additional cybersecurity protection. Also, a hypotube was added to the Exchangeable driveshaft and a coupler was updated to accommodate the change. The hypotube and coupler are located within a fully enclosed, non-patient contacting portion of the device inside the cartridge. The driveshaft continues to be identical in length, material, filar count, tip, and crown to the predicate driveshaft.
Functional and Safety Testing:	Only software verification and associated testing was required as the software updates do not affect the device performance and hardware.

	The hypotube/coupler update does not impact the functionality of the device to ablate the lesion nor its intended use.
Conclusion:	The subject devices are substantially equivalent to the predicate devices and the devices continue to perform as intended.