April 27, 2022

Cardiovascualr Systems Inc.
Kris Miller
Principal Regulatory Specialist
1225 Old Highway 8 NW
New Brighton, Minnesota 55112

Re: K220568
Trade/Device Name: Diamondback 360® Peripheral Orbital Atherectomy System, Stealth 360® Peripheral Orbital Atherectomy System, 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: February 25, 2022
Received: February 28, 2022

Dear Kris 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/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,

For

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)*

K220568

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

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 atherosclerosis disease in peripheral arteries and who are acceptable candidates for percutaneous transluminal atherectomy.
The OAS SOLID, CLASSIC and MICRO crowns support 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 2.00 Max Crown has not been tested to support removal of stenotic material from artificial arteriovenous dialysis fistulae (AV shunt).

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 SOLID, CLASSIC and MICRO crowns support 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 2.00 Max Crown has not been tested to support removal of stenotic material from artificial arteriovenous dialysis fistulae (AV shunt).

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 OAS SOLID, CLASSIC and MICRO crowns support 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 2.00 Max Crown has not been tested to support removal of stenotic material from artificial arteriovenous dialysis fistulae (AV shunt).

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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510(k) Summary

Submitter:	Cardiovascular Systems Inc. (CSI) 1225 Old Highway 8 NW St. Paul, MN 55112
Contact Person:	Kris Miller Principal Regulatory Affairs Specialist Cardiovascular Systems Inc. 1225 Old Highway 8 NW St. Paul, MN 55112 Phone: 612-999-3749 kmiller@csi360.com
Date Prepared:	February 25, 2022
Trade Name:	• Diamondback 360® Peripheral Orbital Atherectomy System • Stealth 360® Peripheral Orbital Atherectomy System • 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(s):	• Diamondback/Stealth = K203008 • Exchangeable = K203008 Reference Device • Predator = K090521

Device Description:	The Diamondback [STEALTH] [Exchangeable Series] Peripheral Orbital Atherectomy Systems (OAS) are designed to remove or reduce occlusive material and restore luminal patency by using an orbiting, diamond-coated, eccentrically mounted crown. The OAS consists of the following main components: 1. Reusable Saline Pump (provided non-sterile) 2. Single-use Orbital Atherectomy Device (OAD) (provided sterile) 3. Single-use Atherectomy lubricant (provided sterile) 4. Single-use Atherectomy guide wire (provided sterile) <u>Mechanism of Action</u> The Diamondback [STEALTH] [Exchangeable Series] 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.
Indications for Use:	*The DIAMONDBACK [STEALTH] [Exchangeable Series] 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 OAS Solid, Classic and Micro crowns support 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 2.00 Max Crown has not been tested to support removal of stenotic material from artificial arteriovenous dialysis fistulae (AV shunt).*

Functional and Safety Testing:	Biocompatibility Testing The biocompatibility evaluation includes the following tests: • Cytotoxicity • Sensitization • Irritation/Intracutaneous Reactivity • Systemic Toxicity • Pyrogenicity • Hemocompatibility Bench Testing The following bench tests were conducted in accordance with applicable standards and guidance. • Stall, Tight Stenosis, Life, Coating Integrity, Tensile Verification Testing • Orbit Characterization Testing • Temperature and Flow Verification Testing • Particulate Testing • Corrosion Testing • GLP Animal 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.

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 • Same vessel diameter range and anatomic location of use • Same principles of operation • Same sterilization method and SAL • Same number of uses per device (single use) • Same performance specifications The only difference between the cleared crown in the predicate device and the currently marketed 2.00 Solid crown is the size of the diamonds used in the crown coating. The currently marketed crowns are coated with 30-micron diamonds whereas the proposed crown will use 70-micron diamonds. The crown diamond coating process is intended to leave approximately one-third of the diamond exposed, such that a 30-micron diamond has about 10-microns exposed as a sanding surface. Therefore, the change from 30-micron to 70-micron diamonds results in an approximately 13-microns in exposed diamond on the crown surface. There is a minor update to the Indications for Use statement as the 2.00 Max Crown has not been tested to support removal of stenotic material from artificial arteriovenous dialysis fistulae (AV shunt). No other changes will be made to the devices. The current 2.00 Solid Crown and the proposed 2.00 Max Crown may be used to treat lesions in larger vessels such as the Superior Femoral Artery (SFA) or Common Femoral Artery (CFA). In these larger vessels, lesions tend to be less calcified.
Conclusion:	The data provided supports substantial equivalence for the Diamondback [STEALTH] [Exchangeable Series] 360® Peripheral Orbital Atherectomy System compared to the predicate device. The testing results demonstrate that the devices perform as intended under the specified use conditions.