September 14, 2021

Cardiovascular Systems Inc.
Kris Miller
Sr. Regulatory Specialist, Regulatory Affairs
1225 Old Highway 8 NW
New Brighton, Minnesota 55112

Re: K210586
Trade/Device Name: Diamondback 360® Peripheral Orbital Atherectomy System, Diamondback 360® Stealth Orbital Atherectomy system
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: August 13, 2021
Received: August 16, 2021

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,

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)*
K210586

Device Name
Diamondback 360® Peripheral Orbital Atherectomy System
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.

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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K210586 510(K) SUMMARY

Submitter:	Cardiovascular Systems, Inc. 1225 Old Highway 8 NW Saint Paul, MN 55112
Contact Person:	Kris Miller Sr. Regulatory Specialist Cardiovascular Systems, Inc. 1225 Old Highway 8 NW St. Paul, MN 55112 Ph: 612-999-3749 kmiller@csi360.com
Date Prepared:	February 25, 2021
Trade Name:	Diamondback 360® Peripheral Orbital Atherectomy System, Stealth 360® Peripheral Orbital Atherectomy System
Common Name:	Intraluminal Artery Stripper
Regulation Number:	870.4875
Classification:	Class II
Product Code:	MCW
Predicate Device(s):	K190634 - Diamondback 360 [Stealth] Peripheral Orbital Atherectomy System (Cardiovascular Systems, Inc.)
Device Description:	The Diamondback 360 and Stealth 360 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) Mechanism of Action The Diamondback and Stealth OAS mechanism of action 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 360® [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.
Comparison to Predicate Device:	The modified Diamondback and Stealth OAS devices is identical to the predicate device as follows: • Same regulation number, product code and classification • Same intended use and indications for use • Same principles of operation • Same 0.014" guidewire compatibility • Same sterilization method and SAL • Same number of uses per device (single use) The modified Diamondback and Stealth OAS device is different from the predicate device as follows: • Alternate supplier for the current motor • Alternate supplier for the current driveshaft bearings. The new bearings have a lower specification from an ABEC tolerance from ABEC 7P to ABEC3 that aligns with the short duration of use of our device. A change in the grease used in the bearing from a LY75 to LY551 is included in this change.
Functional and Safety Testing:	The following testing was performed to confirm pre-determined device specifications were met:

	• Start-Up Torque test • Dynamic Stall test • OAD Life test o Sound Level Verification • Tight Stenosis test (as needed, based on results of stall test)
Conclusion:	Testing demonstrates substantial equivalence. No new questions of safety or effectiveness were identified compared to the predicate device.