July 2, 2019

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

Re: K190634
Trade/Device Name: Diamondback 360 Peripheral Orbital Atherectomy System, Stealth 360 Peripheral Orbital Atherectomy System
Regulation Number: 21 CFR 840.4875
Regulation Name: Intramural Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: May 28, 2019
Received: May 29, 2019

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/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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190634

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.

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

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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
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Cardiovascular Systems Inc.
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Date Prepared: March 8, 2019

510(k) Number: K190634

Trade Name: Diamondback 360® Peripheral Orbital Atherectomy System
Stealth 360® Peripheral Orbital Atherectomy System

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 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 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 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.

Technologic Characteristic Comparison:

	DiamondBack (Predicate Device) K152694	**Proposed Device DiamondBack OAS**	**Proposed Device Stealth OAS**	**Impact of Difference on Safety and Effectiveness**
Crown Styles	Micro Solid Classic	Same as predicate	**1.25 Micro crown is new to Stealth. Solid and Classic are same as predicate**	No Impact to Safety and Effectiveness as this crown style is identical to the predicate device.
Crown Sizes (mm)	1.25 1.50 1.75 2.00	Same as predicate	**1.25 Micro crown is new to Stealth. All other sizes are the same as predicate.**	No Impact to Safety and Effectiveness as this crown size is identical to the predicate device.

	DiamondBack (Predicate Device) K152694	Proposed Device DiamondBack OAS	Proposed Device Stealth OAS	Impact of Difference on Safety and Effectiveness
OAD driveshaft lengths (mm)	145 180 200	Same as predicate	Same as predicate	NA – No difference
OAD driveshaft diameter (in.)				
1.25Micro145	.0285	Same as predicate	**New to Stealth (same as predicate)**	No Impact to Safety and Effectiveness as this is comparable to the currently marketed 1.25MICRO145
1.25Solid145	.029	Same as predicate	Same as predicate	NA – No difference
1.50Solid145	.029	Same as predicate	Same as predicate	NA – No difference
2.00Solid145	.031	Same as predicate	Same as predicate	NA – No difference
1.50Classic145	.0335	Same as predicate	Same as predicate	NA – No difference
2.00Classic145	.0335	Same as predicate	Same as predicate	NA – No difference
1.25Solid200	.029	Same as predicate	Same as predicate	NA – No difference
1.50Solid200	.029	Same as predicate	Same as predicate	NA – No difference
1.75Solid180	.029	Same as predicate	Same as predicate	NA – No difference
Sheath Size				
1.25Micro145	4 Fr	Same as predicate	Same as predicate	No Impact to Safety and Effectiveness as this is comparable to the currently marketed 1.25MICRO145
1.25Solid145	4 Fr	Same as predicate	6 Fr	The Stealth sheath size is unchanged from

	DiamondBack (Predicate Device) K152694	Proposed Device DiamondBack OAS	Proposed Device Stealth OAS	Impact of Difference on Safety and Effectiveness
				the currently cleared device.
1.50Solid145	5 Fr	Same as predicate	6 Fr	The Stealth sheath size is unchanged from the currently cleared device.
2.00Solid145	5 Fr	Same as predicate	6 Fr	The Stealth sheath size is unchanged from the currently cleared device.
1.50Classic145	5 Fr	Same as predicate	6 Fr	The Stealth sheath size is unchanged from the currently cleared device.
2.00Classic145	5 Fr	Same as predicate	6 Fr	The Stealth sheath size is unchanged from the currently cleared device.
1.25Solid200	5 Fr	Same as predicate	Same as predicate	NA – No difference
1.50Solid200	5 Fr	Same as predicate	Same as predicate	NA – No difference
1.75Solid180	5 Fr	Same as predicate	Same as predicate	NA – No difference
Filar Count(x) and Wire Diameter				
1.25Micro145	3x.0061	Same as predicate	Same as predicate	NA – No difference
1.25Solid145	3x.0067	Same as predicate	Same as predicate	NA – No difference
1.50Solid145	3x.0067	Same as predicate	Same as predicate	NA – No difference
2.00Solid145	6x.0060	Same as predicate	Same as predicate	NA – No difference
1.50Classic145	3x.0070	Same as predicate	Same as predicate	NA – No difference
2.00Classic145	3x.0070	Same as predicate	Same as predicate	NA – No difference

	DiamondBack (Predicate Device) K152694	Proposed Device DiamondBack OAS	Proposed Device Stealth OAS	Impact of Difference on Safety and Effectiveness
1.25Solid200	7x.0060	Same as predicate	Same as predicate	NA – No difference
1.50Solid200	7x.0060	Same as predicate	Same as predicate	NA – No difference
1.75Solid180	7x.0060	Same as predicate	Same as predicate	NA – No difference
Rotational Speed Range	Low (60 kRPM) Medium (90 kRPM) High (120 kRPM) High (140 kRPM - classic crowns only)	Same as predicate	Same as predicate	NA – No difference
GllideAssist	(cleared in K182397)	Same as predicate	1.25MICRO145 only	No impact. This function was cleared in K182397.
Sterile	Yes	Same as predicate	Same as predicate	NA – No difference
Single Use	Yes	Same as predicate	Same as predicate	NA – No difference
Used in conjunction with	• OAS Saline Pump • CSI Peripheral Guide Wires • ViperSlide Lubricant	Same as predicate	Same as predicate	NA – No difference

Performance Data:

Bench Testing

The following bench tests were conducted in accordance with applicable standards and guidance.

- Track Verification Testing
- Stall / Life and Tight Stenosis Verification Testing
- Device Pre-Conditioning Verification Testing
- Tensile Verification Testing
- Temperature and Saline Flow Verification Testing
- Glide Start Up Verification Testing
- Software Verification
- Electromagnetic Compatibility
- Electrical Safety

Performance data and software verification was collected and verified that the design meets all product specifications and address the potential safety hazards that have been identified.

Conclusion:

The Diamondback 360 Peripheral Orbital Atherectomy System and the Stealth 360 Peripheral Orbital Atherectomy System have the same indications for use and the same technological characteristics as the predicate device. The testing results demonstrate that the devices perform as intended under the specified use conditions. Based on this and data provided in this pre-market notification, the subject and predicate devices have been shown to be substantially equivalent.