October 01, 2021

Cardiovascular Systems Inc.
Kim Wallner
Senior Regulatory Affairs Specialist
1225 Old Highway 8 NW
Saint Paul, Minnesota 55112

Re: K152694
Trade/Device Name: Diamondback 360 Peripheral Orbital Atherectomy System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal artery stripper
Regulatory Class: Class II
Product Code: MCW

Dear Kim Wallner:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 21, 2015. Specifically, FDA is updating this SE Letter because of a typo in the 510(k) Summary header, as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, gregory.oconnell@fda.hhs.gov.

Sincerely,

For Sara M. Royce -S
Digitally signed by Sara M. Royce -S
Date: 2021.10.01 13:43:30 -04'00'

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 21, 2015

Cardiovascular Systems, Inc.
Ms. Kim Wallner
Senior Regulatory Affairs Specialist
1225 Old Highway 8 NW
Saint Paul, MN 55112

Re: K152694
Trade/Device Name: Diamondback 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 18, 2015
Received: September 21, 2015

Dear Ms. Wallner:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152694

Device Name
Diamondback 360 Peripheral Orbital Atherectomy Sytstem

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 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.

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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Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Company Name:	Cardiovascular Systems, Inc. 1225 Old Highway 8 NW Saint Paul, MN 55112
Contact:	Kim Wallner
Phone:	(651) 202-4917
Fax:	(651) 305-7734

Summary Date:	September 18, 2015
Trade Name:	Diamondback 360® Peripheral Orbital Atherectomy System
Product Code:	MCW—Catheter, Peripheral, Atherectomy
Classification Regulation:	21 CFR 870.4875—Intraluminal Artery Stripper
Classification:	II

Primary Predicate Device:

510(k) Number:	K110389
Manufacturer:	Cardiovascular Systems, Inc.
Trade Name:	Stealth 360°® Orbital PAD System

Reference Devices:

510(k) Numbers:	K122987, K131092, K151260
Manufacturer:	Cardiovascular Systems, Inc.
Trade Name:	Stealth 360°® Orbital PAD System

510(k) Number:	K150732, K151260
Manufacturer:	Cardiovascular Systems, Inc.
Trade Name:	Diamondback 360® Peripheral Orbital Atherectomy System

Description of Device

The Diamondback 360 Peripheral Orbital Atherectomy System (OAS) is intended for use in the treatment of peripheral arteries and A-V graft (shunt) stenosis.

The OAS provides a method of removing stenotic material from peripheral arteries and A-V grafts. The Diamondback 360 uses an eccentrically rotating sanding surface (crown) to remove stenotic material on the vessel wall. The stenotic particles that are removed are small enough to be absorbed by the body.

The Diamondback 360 Peripheral Orbital Atherectomy System consists of the following components:

1) Orbital Atherectomy Device (OAD)
2) Atherectomy Guide Wire (e.g., ViperWire Advance)
3) Saline Infusion Pump (SIP)
4) Atherectomy Lubricant (e.g., ViperSlide)

Description of Change

The 1.50 Solid Peripheral Orbital Atherectomy Device was modified to reduce the diameter of the shaft (drive shaft, drive shaft tip bushing, and saline sheath) including modification of the crown for compatibility with the smaller diameter drive shaft. In addition, the saline sheath material and design for the 1.50 Solid, 2.00 Solid, 1.50 Classic and 2.00 Classic OAD configurations were changed and an updated glue plug component was added to accomodate the new saline sheath design.

Intended Use

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 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.

Technology

The Diamondback 360 Peripheral Orbital Atherectomy System provides a method of removing or reducing occlusive atherosclerotic or stenotic material. The OAS applies a diamond coated, eccentrically rotating sanding surface to remove stenotic material on the vessel wall. The stenotic particles that are removed are small enough to be absorbed by the body. This is the same technology that was cleared to market for use in the peripheral arteries for Stealth 360

Orbital PAD System in 510(k) K110389, K122987, and K131092 and for Diamondback 360 Peripheral OAS in 510(k) K150732.

Performance Data

The Diamondback 360 Peripheral Orbital Atherectomy System was evaluated using the following performance bench testing to confirm the performance characteristics as compared to the predicate device.

- System Life Testing including guide wire
- Stall Testing
- Introducer Compatibility Testing
- Temperature Testing
- Tensile Testing
- Flexibility Testing
- Delivered Torque Testing
- Orbit Testing
- Guide Wire Brake Testing
- Saline Flow Testing
- Track Testing
- Packaging/Simulated Distribution Testing
- Biocompatibility
    - Cytotoxicity per ISO 10993-5
    - ASTM Hemolysis per ISO 10993-4
    - Chemical Characterization per ISO 10993-18

All test results demonstrate that the materials chosen, the manufacturing process, and the design utilized for the Diamondback 360 Peripheral Orbital Atherectomy System met the established specifications necessary for consistent performance during its intended use.

Conclusions

The Diamondback 360 Peripheral Orbital Atherectomy System met all predetermined acceptance criteria of design verification and validation testing as specified by applicable standards, test protocols, and/or customer inputs. Testing results demonstrate that the Diamondback 360 Peripheral Orbital Atherectomy System is substantially equivalent to the legally marketed predicate devices and does not raise any new safety or effectiveness questions.