



Food and Drug Administration
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June 10, 2015

Cardiovascular Systems, Inc.
c/o Ms. Kim Wallner
Senior Regulatory Affairs Specialist
1228 Old Highway 8 NW
Saint Paul, MN 55112

Re: K151260

Trade/Device Name: Stealth 360 Orbital PAD System and 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: May 11, 2015
Received: May 12, 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

Indications for Use

510(k) Number (if known)

K151260

Device Name

Stealth 360 Orbital PAD System and Diamondback 360 Peripheral Orbital Atherectomy System

Indications for Use (Describe)

The Stealth 360 Orbital PAD System and the Diamondback 360 Peripheral Orbital Atherectomy System are percutaneous orbital atherectomy systems 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.

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Section. 6 510(k) Summary

Company Name: Cardiovascular Systems, Inc.
1225 Old Highway 8 NW
Saint Paul, MN 55112

Contact: Kim Wallner

Phone: (651) 202-4917

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Summary Date: May 11, 2015

Trade Name: ViperWire Advance Flex Tip Peripheral Guide Wire
(OAS component that is part of the: Stealth 360 Orbital PAD System
and Diamondback 360 Peripheral Orbital Atherectomy System)

Product Code: MCW—Catheter, Peripheral, Atherectomy

Classification Regulation: 21 CFR 870.4875—Intraluminal Artery Stripper

Classification: II

Predicate Devices:

510(k) Numbers:	K110389, K122987, K131092
Manufacturer:	Cardiovascular Systems, Inc.
Trade Name:	Stealth 360 Orbital PAD System
510(k) Number:	K133399, K150732
Manufacturer:	Cardiovascular Systems, Inc.
Trade Name:	Diamondback 360 Peripheral Orbital Atherectomy System

6.1 Description of Device

The atherectomy guide wire is a component that is part of the Stealth 360 Orbital PAD System and Diamondback 360 Peripheral Orbital Atherectomy System. The Stealth 360 Orbital PAD System and the Diamondback 360 Peripheral Orbital Atherectomy System (OAS) are 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 Stealth 360 and the Diamondback 360 use 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.

In addition to the atherectomy guide wire, the Stealth 360 Orbital PAD System and the Diamondback 360 Peripheral Orbital Atherectomy System consists of the following components: Orbital Atherectomy Device (OAD), Saline Infusion Pump, and Atherectomy Lubricant (e.g., ViperSlide).

6.2 Description of Change

The guide wire was modified to update the distal spring tip, coil material, and core wire diameter.

6.3 Intended Use

The Stealth 360 Orbital PAD System and the Diamondback 360 Peripheral Orbital Atherectomy System are percutaneous orbital atherectomy systems 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.

6.4 Technology

The Stealth 360 Orbital PAD System and the Diamondback 360 Peripheral Orbital Atherectomy System provide 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.

The ViperWire Advance Flex Tip Guide Wire is a smooth, stainless steel wire, with a silicone coating, and a radiopaque distal spring tip. The guide wire allows for proper

positioning of the device crown within peripheral arteries and provides a center of rotation for the device drive shaft.

This is the same technology that was cleared to market for use in the peripheral arteries for Stealth 360 Orbital PAD in 510(k) K110389, K122987, K131092 and for Diamondback 360 Peripheral OAS per K133399 and K150732.

6.5 Performance Data

The ViperWire Advance Flex Tip Guide Wire was evaluated using the following performance bench testing to confirm the performance characteristics as compared to the predicate device.

- Corrosion Testing
- Life Testing
- Tensile Strength
- Tip Flexibility
- Trackability
- Orbit Testing
- Torque Transfer
- Combined Load Testing
- Packaging/Simulated Distribution Testing
- Biocompatibility
 - Cytotoxicity per ISO 10993-5
 - Systemic Toxicity per ISO 10993-11
 - Sensitization per ISO 10993-10
 - Irritation per ISO 10993-10
 - Pyrogenicity per ISO 10993-11
 - Hemocompatibility per ISO 10993-4

All test results demonstrate that the materials chosen, the manufacturing processes, and the design utilized for the ViperWire Advance Flex Tip Guide Wire met the established specifications necessary for consistent performance during its intended use.

6.6 Conclusion

The ViperWire Advance Flex Tip Guide Wire 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 ViperWire AdvanceFlex Tip Guide Wire used with the Stealth 360 Orbital PAD System and Diamondback 360 Peripheral Orbital Atherectomy System is substantially equivalent to the legally marketed predicate device, does not raise any new safety or effectiveness questions, and performs as well or better than the predicate device.