

Section. 6 510(k) Summary

JUL 26 2011

Company Name: Cardiovascular Systems, Inc.
651 Campus Drive
Saint Paul, MN 55112

Contact: Megan M. Brandt

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Summary Date: May 16, 2011

Trade Name: Diamondback 360[®] Orbital Atherectomy System with ViperSlide[®]
Lubricant

Common Name: Peripheral Atherectomy Device

Classification Name: Peripheral Atherectomy Catheter (21 CFR 870.4875; Product Code:
MCW)

Predicate Devices:

510(k) Number: K071350
Manufacture: Cardiovascular Systems, Inc.
Trade Name: Diamondback 360[®] Orbital Atherectomy System

510(k) Number: K071427
Manufacture: Cardiovascular Systems, Inc.
Trade Name: Diamondback 360[®] Orbital Atherectomy System

510(k) Number: K082981
Manufacture: Cardiovascular Systems, Inc.
Trade Name: Diamondback 360[®] Orbital Atherectomy System
with ViperSlide Lubricant

510(k) Number: K090521
Manufacture: Cardiovascular Systems, Inc.
Trade Name: Diamondback Predator 360[®] Orbital Atherectomy
System

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

6.1 Description of Device

The Diamondback 360° Orbital Atherectomy System with ViperSlide is an orbital atherectomy system (OAS) that 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 OAS applies a diamond coated, eccentrically rotating surface to ablate stenotic material. The stenotic particles that are removed are small enough to be absorbed by the body.

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

- 1) Orbital atherectomy device (OAD, air or electric powered)
- 2) Atherectomy guide wire
- 3) Atherectomy saline pump or controller
- 4) Atherectomy lubricant

6.2 Intended Use

The Diamondback 360° 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.

6.3 Technology

The Diamondback 360° Orbital Atherectomy System with ViperSlide provides a method of removing occlusive atherosclerotic or stenotic material. The OAS applies a diamond coated, eccentrically rotating surface to ablate stenotic tissue. The ViperSlide lubricant is a lipid emulsion with soybean oil, egg phospholipid, and glycerin prepared with water for injection. ViperSlide is mixed with saline prior to treatment and acts as a lubricant to cool the OAD during use.

This 510(k) specifically addresses the addition of an alternate ViperSlide lubricant formulation for use with the Diamondback 360° Orbital Atherectomy System. The OAS technologies described in the previous submissions remain unchanged since the lubricants are interchangeable. The alternate ViperSlide formulation design and components are substantially equivalent to the predicate devices. The use of lubricant with the Diamondback 360° OAS was cleared to market for use in peripheral arteries in 510(k) K071350 and K082981, Predator 360° (originally cleared as 3X) per K090521, Stealth 360° per K110389, and for use in A-V grafts in 510(k) K071427.

6.4 Performance Data

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

- System Life Testing
- Emulsion Admixture Stability

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

Biocompatibility testing on the proposed Diamondback 360° Orbital Atherectomy System with ViperSlide has been completed. The biocompatibility test results show that the materials used in the design and manufacture of ViperSlide are biocompatible with the biological tissue consistent with its intended use. The following biocompatibility tests were completed.

- ISO MEM Elution Assay
- Hemolysis – Direct Contact Method
- In-vitro Hemocompatibility Assay
- ISO Acute Systemic Injection Test

6.5 Conclusions

The Diamondback 360° Orbital Atherectomy System with ViperSlide 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° Orbital Atherectomy System with ViperSlide is substantially equivalent to the legally marketed predicate device and does not raise any new safety or effectiveness questions.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Cardiovascular Systems, Inc.
c/o Megan M. Brandt
651 Campus Dr.
St. Paul, MN 55112

JUL 26 2011

Re: K111388

Trade/Device Name: Diamondback 360 Orbital Atherectomy System (OAS) with ViperSlide
Regulation Number: 21 CFR 870.4875
Regulation Name: Peripheral Atherectomy Catheters
Regulatory Class: Class II
Product Code: MCW
Dated: May 16, 2011
Received: May 17, 2011

Dear Ms. Brandt:

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

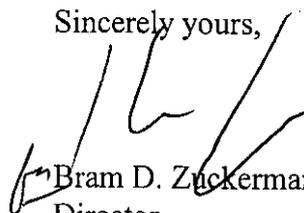
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



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): K111388

Device Name: Diamondback 360® Orbital Atherectomy System with ViperSlide® Lubricant

Indications For Use:

The Diamondback 360° 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.

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111388