

AUG 30 2007

Section 5 – 510(k) Summary

Submitter:	Cardiovascular Systems, Inc 651 Campus Drive, St. Paul, MN 55112
Contact Person:	Cindy Setum, Ph.D., Vice President, Clinical Affairs phone: 651-259-1650, fax: 651-259-1697
Date Prepared:	May 22, 2007
Trade Name:	Diamondback 360°™ Orbital Atherectomy System for Treatment of A-V Shunt Stenosis
Classification:	Class II Peripheral Atherectomy Catheter 21 CFR §870.4875
Product Code:	MCW
Predicate Device(s):	The subject device is equivalent to the following device: K041630, Orbital Atherectomy System for Treatment of A-V Shunt Stenosis
Device Description:	The Diamondback 360°™ Orbital Atherectomy System (OAS) is intended for use in treatment of artificial arteriovenous dialysis fistula stenosis. An artificial arteriovenous dialysis fistula (A-V shunt) is placed sub-dermal to support kidney dialysis. A consequence of the body's reaction to the foreign material of the A-V shunt is to form clots and neointimal stenosis of the A-V Shunt. The most common location for the A-V shunt stenosis is at the shunt to vein anastomosis. It is this region that the Cardiovascular Systems, Inc. Orbital Atherectomy System (CSI OAS) is applied to remove neointimal tissue causing a stenosis in the A-V shunt.
Intended Use:	The Orbital Atherectomy System supports removal of stenotic material from artificial arteriovenous dialysis fistulae (A-V Shunts).
Functional and Safety Testing:	To verify that device design met its functional and performance requirements, representative sample of the device underwent mechanical testing and biocompatibility in accordance with ISO 10993.
Conclusion:	Cardiovascular Systems, Inc. considers the Diamondback 360°™ Orbital Atherectomy System to be equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Cardiovascular Systems, Inc.
c/o Michael J. Kallok, Ph.D.
Chief Scientific Officer
651 Campus Drive
St. Paul, MN 55112-3495

Re: K071427
Diamondback 360™ Orbital Atherectomy System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal artery stripper
Regulatory Class: Class II (Two)
Product Code: MCW
Dated: August 3, 2007
Received: August 6, 2007

Dear Dr. Kallok:

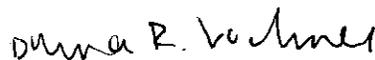
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 – Indications For Use Statement

510(k) Number (if known): K071427

Device Name: Diamondback 360°™ Orbital Atherectomy System for Treatment of A-V Shunt Stenosis

Indications for Use:

The Orbital Atherectomy System supports removal of stenotic material from artificial arteriovenous dialysis fistulae (A-V Shunts).

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 THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Danna R. Vachner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071427