K110389

MAR 1 1 2011

Section. 6 510(k) Summary

Company Name:	Cardiovascular Systems, Inc. 651 Campus Drive Saint Paul, MN 55112
Contact:	Megan M. Brandt
Phone:	(651) 259-2805
Fax:	(651) 305-7734
Summary Date:	February 9, 2011
Trade Name:	Stealth 360™ Orbital PAD System
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:	K090521
Manufacture:	Cardiovascular Systems, Inc.
Trade Name:	Diamondback Predator 360® Orbital Atherectomy System

6.1 Description of Device

The Stealth 360™ Orbital PAD System 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 Stealth 360° uses an electrically driven shaft to apply a diamond coated, eccentrically rotating sanding surface to ablate stenotic material. The stenotic particles that are removed are small enough to be absorbed by the body.

The Stealth 360° Orbital PAD System consists of the following components:

1) Orbital atherectomy device
2) Atherectomy guide wire
3) Externally operated saline pump
4) Atherectomy Lubricant (e.g. ViperSlide)

6.2 Intended Use

The Stealth 360° Orbital PAD 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 Stealth 360° Orbital PAD System provides a method of removing occlusive atherosclerotic or stenotic material. The OAS applies a diamond coated, eccentrically rotating sanding surface to ablate stenotic tissue. The stenotic particles that are removed are small enough to be absorbed by the body. This same technology was cleared to market for use in peripheral arteries in 510(k) K071350 and Predator 360° (originally cleared as 3X) per K090521. The primary difference is that the drive shaft containing the sanding crown is driven by a brushless electric motor rather than an air turbine (energy type). The Stealth 360° is available in both Predator Solid crown and Diamondback Classic crown models.

6.4 Performance Data

Biocompatibility testing on the proposed Stealth 360° Orbital PAD System has been completed. The biocompatibility test results show that the materials used in the design and manufacture of the components of the proposed device are non-toxic and non-sensitizing to biological tissue consistent with its intended use. The following biocompatibility tests were completed.

- ISO MEM Elution Assay
- ASTM Hemolysis Assay
- Material Mediated Rabbit Pyrogenicity
- ISO Guinea Pig Maximization Sensitization
- ISO Acute Systemic Injection Test
- ISO Intracutaneous Reactivity Test
- Complement Activation C3a and SC5b-9 Assay
- Partial Thromboplastin Time

The proposed Stealth 360° Orbital PAD System was evaluated using the following performance bench testing to confirm the performance characteristics as compared to the predicate device.

- System Life Testing
- Stall Testing
- Introducer Compatibility Testing
- Temperature Testing
- Tensile Testing
- Flexibility Testing
- Delivered Torque Testing
- Orbit Testing

- Device User Interface Controls Testing
- Switch Logic Testing
- Guide Wire Brake Testing
- Flow Testing
- AV Graft Testing
- Motor Control Board Testing
- Track Testing
- Package Testing (Handle and Pump)
- EN 60601-1 Electrical Testing (Handle and Pump)
- EN 60601-1-2 EMC Testing (Handle and Pump)
- Saline Pump Functional Testing
- Saline Pump Physical Testing

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

6.5 Conclusions

The Stealth 360° Orbital PAD 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 Stealth 360° Orbital PAD System 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 Ms. Megan Brandt
Regulatory Affairs Manager
651 Campus Drive
St. Paul, MN 55112

MAR 1 1 2011

Re: K110389
Trade/Device Name: Stealth 360 Orbital PAD System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: February 9, 2011
Received: February 10, 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. However, we remind you 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 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 Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section. 5 Indications for Use Statement

510(k) Number: K110389

Device Name: Stealth 360™ Orbital PAD System

Indications for Use:

The Stealth 360° Orbital PAD 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.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vo Thuc

(Division Sign-Off)
Division of Cardiovascular Devices

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