DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 14, 2015

Avinger, Inc.
c/o Ms. Patty Hevey
Vice President, Clinical and Regulatory Affairs
400 Chesapeake Drive
Redwood City, CA 94063

Re: K152275
Trade/Device Name: Pantheris System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW, NQQ
Dated: August 11, 2015
Received: August 12, 2015

Dear Ms. Hevey:

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

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)*
K152275

Device Name
Pantheris System

Indications for Use *(Describe)*
The Pantheris System is intended to remove plaque (atherectomy) from partially occluded vessels in the peripheral vasculature with a reference diameter of 3.0 mm to 7.0 mm, using OCT-assisted orientation as an adjunct to fluoroscopy.

The Pantheris System is NOT intended for use in the iliac, coronary, cerebral, renal or carotid vasculature.

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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1.0 510(K) SUMMARY

510(k) Notification K152275

GENERAL INFORMATION

Applicant:

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Redwood City, CA 94063
U.S.A.
Phone: 650-241-7900
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Contact Person:

Patty Hevey
Vice President, Clinical and Regulatory Affairs
Avinger, Inc.
Phone: 650-222- 3666
Fax: 650-241-7901

Date Prepared:

August 11th, 2015

DEVICE INFORMATION

Trade Name:

Pantheris System

Generic/Common Name:

Peripheral Atherectomy Catheter

Classification:

21 CFR§870.4875, Intraluminal Artery Stripper, Class II
21 CFR§892.1560, Ultrasonic Pulsed Echo Imaging System, Class II

Product Codes:

MCW, NQQ

PREDICATE DEVICES

- Medtronic, Inc. (formerly Fox Hollow Technologies) SilverHawk Peripheral Plaque Excision System (K061188)
- Avinger Ocelot System (K140185)

DEVICE DESCRIPTION

The Pantheris System consists of the Pantheris Catheter (packaged with the Flush Fixture), Lightbox Sled (referred to as Sled), the Lightbox HS Imaging Console, the Lightbox Umbilical (referred to as Umbilical), Sterile Drape (accessory) and the Occlusion Sheath (optional accessory). The Pantheris System combines the use of Avinger's Optical Coherence Tomography (OCT) technology with peripheral vascular atherectomy capabilities.

The Pantheris Catheter has a working length of 130 cm and is a sterile, single-use device that is compatible with 8F sheaths and 0.014" guidewires. The Pantheris Catheter consists of an imaging assembly, a rotating cutter, an apposition mechanism (balloon) and a flexible, tiltable nosecone. It also incorporates an Optical Fiber that allows for real-time OCT guided directional atherectomy during the procedure. The Pantheris Catheter and optional Occlusion Sheath accessory are provided sterile and are intended for single-use only.

The Pantheris Catheter is connected to the Lightbox HS Imaging Console via the Sled and the Umbilical. The Sled provides optical and rotational power to the Pantheris Catheter. The Umbilical is a 3-meter long optical and electrical extension cable that connects the Sled to the Lightbox HS Imaging Console.

The Lightbox HS Imaging Console is an optical transceiver, transmitting light to the intraluminal environment through the optical fiber on the Pantheris Catheter and receiving and interpreting the signal from the tissue using a PC-based processing system. The Lightbox provides a visualization platform that allows for real-time OCT-assisted directional atherectomy. The Lightbox HS Imaging Console consists of a cart with two monitors; a PC based processing system, an isolation transformer and an OCT system.

INDICATIONS FOR USE

The Pantheris System is intended to remove plaque (atherectomy) from partially occluded vessels in the peripheral vasculature with a reference diameter of 3.0 mm to 7.0 mm, using OCT-assisted orientation as an adjunct to fluoroscopy. The Pantheris System is NOT intended for use in the iliac, coronary, cerebral, renal or carotid vasculature.

SUBSTANTIAL EQUIVALENCE

The Pantheris System intended use, technological characteristics and principles of operation are similar to the Avinger Ocelot System (K140185) and the Medtronic SilverHawk Peripheral Plaque Excision System (K061188) with the exception of the following:

- Catheter working length
- Distal catheter outer diameter
- Minimum vessel diameter access
- Method of vessel apposition
- Method of distal catheter deflection
- Cutting component speed
- Length of excised cut
- Catheter OCT element

Any differences between the Pantheris System and the predicate devices do not alter the intended use of the Pantheris System. The significance of the differences between the Pantheris System and the predicate devices was evaluated in the VISION clinical trial.

NONCLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary performance testing was conducted on the Pantheris System to support a determination of substantial equivalence to the predicate devices. The nonclinical testing conducted on the Pantheris System provided in the IDE G130159 submission and remaining applicable to the current Pantheris System includes:

- Pantheris design verification and validation studies
- Packaging and shelf-life
- Biocompatibility
- Sterilization
- Software verification and validation
- Electrical safety, electromagnetic compatibility, and laser safety testing
- Pantheris GLP Animal Safety and Performance Report

The collective results of the non-clinical testing demonstrate that the Pantheris System meets the established specifications necessary for consistent performance for its intended use.

CLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

The VISION Study is a prospective, multi-center, non-randomized study to evaluate the safety and effectiveness of the Pantheris System. The primary effectiveness endpoint of this study was technical success, defined as the percent of target lesions

that have a residual diameter stenosis ≤ 50% post the Pantheris device alone as assessed by an independent Angiographic Core Laboratory.

The primary safety endpoint is defined as freedom from a composite of major adverse events (MAEs) through 6-Month follow-up as adjudicated by an independent Clinical Events Committee (CEC). Secondary effectiveness endpoints include, procedural success, defined as the percent of target lesions that have residual diameter stenosis ≤ 30% post-Pantheris and/or any other adjunctive therapy, determined by independent Angiographic Core Laboratory, Ankle-Brachial Index (ABI), Rutherford Classification and quality of life measures using both SF-12 and VascuQoL questionnaires at 30 days and 6 months.

Secondary safety endpoints include freedom from MAE through 30 days, freedom from procedural related emboli and freedom from target vessel revascularization (TVR) through 30 days and 6 months.

The data in this report will present all subjects enrolled in the VISION Study (n=162 subjects; 134 subjects in the Intention-To-Treat (ITT) Cohort and 28 subjects in the Roll-In Cohort) through 30 days with the primary focus on the 130 Per Protocol Cohort subjects who underwent atherectomy with the Pantheris Catheter.

A total of 162 subjects were enrolled in the VISION Study. The treated population consisted of subjects presenting with documented symptomatic atherosclerotic plaque (stenosis ≥70% by visual estimation) who met all eligibility criteria. The primary disease had to be located in reference vessel diameters of ≥3.0 mm and ≤7.0 and not exceed ≤15 cm in length. Subjects were followed through 30-days and six months post-procedure.
Primary safety and effectiveness endpoints were based on an independent Clinical Events Committee (CEC) and independent angiographic Core lab reviews, respectively. The Pantheris System successfully excised plaque below the pre-specified target stenosis of ≤ 50% in 96% (158/164) of lesions treated; meeting the primary effectiveness performance goal of 92.13% with a lower 95% confidence bound of 87%, indicating the primary effectiveness endpoint was met. A total of twenty (20) safety events were identified by the Clinical Events Committee (CEC) resulting in an overall safety event rate of 21.5% (20/93) in the per protocol population (78.5% event free); meeting the safety performance goal of 35.3% with a 95% 1-sided upper confidence bound of 43.2%, indicating the primary safety endpoint was also met.

The secondary efficacy endpoint defined as the percent of target lesions that have a residual diameter stenosis of ≤30% residual stenosis post Pantheris and any other adjunctive therapy was achieved in 79.3% of lesions.
The secondary safety endpoints defined as freedom from MAEs through 30 days, including procedural emboli and clinically driven target vessel revascularization

(TVR) as adjudicated by an independent CEC, further confirmed that the device has provided clinical improvement in subjects' clinical status over time.

The study endpoints achieved the effectiveness performance goals while demonstrating a safety profile indicating the Pantheris Catheter can be used to safely excise plaque from lower extremity arteries with precision. The study results also demonstrate low acute device related adverse events.

CONCLUSION

The results of the non-clinical and clinical testing demonstrate that the Pantheris System is as safe and effective as the predicate devices. The clinical testing demonstrates that the technological characteristics employed by the Pantheris System do not raise any new issues of safety or effectiveness. Therefore, the Pantheris System is substantially equivalent to the identified predicate devices.