DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 18, 2016

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

Re: K162326
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 17, 2016
Received: August 19, 2016

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Brian D. Pullin -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)*
K162326

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 3.0mm to 7.0mm, using OCT-assisted orientation and imaging. The system is an adjunct to fluoroscopy by providing images of vessel lumen, wall structures and vessel morphologies.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1.0 510(K) SUMMARY

510(k) Notification K162326

GENERAL INFORMATION

Applicant:

Avinger, Inc.
400 Chesapeake Drive
Redwood City, CA 94063
U.S.A.
Phone: 650-241-7900
Fax: 650-241-7901

Contact Person:

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

Date Prepared:

October 17th 2016

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

- Primary Predicate Device – **Avinger Pantheris System** (K160827), hereafter referred to as the **current Pantheris System**
- Secondary Predicate Device – **Avinger Pantheris System** (K152275), hereafter referred to as the **initial Pantheris System**
- Secondary Predicate Device - **Avinger Ocelot System** (K140185), hereafter referred to as the **Ocelot System**

DEVICE DESCRIPTION

The current Pantheris System (K160827), listed as the primary predicate device, consists of the Pantheris Catheter, Lightbox Sled with integrated Umbilical (referred to as "Sled") the Lightbox HS Imaging Console (referred to as "Lightbox") and the accessories that are packaged with the Pantheris Catheter: flush fixture, tweezers, syringes and stopcocks, and a Sterile Drape accessory that is packaged separately. The subject Pantheris System submitted as part of this 510(k) submission does not introduce any changes to the device specifications, materials or manufacturing processes and is identical to the current Pantheris System.

The Pantheris System combines the use of Avinger's Optical Coherence Tomography (OCT) technology (identical to the OCT Technology used in the Ocelot System (K140185)) with peripheral vascular atherectomy capabilities.

The Pantheris Catheter comes in both a 7Fr and 8Fr size. Both sizes have a working length of 110 cm and are sterile, single-use devices that are compatible with 7Fr and 8Fr sheaths (respectively) and 0.014" guidewires. The Pantheris Catheter incorporates an Optical Fiber that allows for real-time OCT guided directional atherectomy during the procedure.

The Pantheris Catheter is connected to the Lightbox via the Sled. The Lightbox 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 for the real-time OCT-assisted directional atherectomy. The Lightbox consists of a cart with two monitors; a PC based processing system, an isolation transformer and an OCT system.

PROPOSED 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 3.0mm to 7.0mm, using OCT-assisted orientation and imaging. The system is an adjunct to fluoroscopy by providing images of vessel lumen, wall structures and vessel morphologies. The Pantheris System is NOT intended for use in the iliac, coronary, cerebral, renal or carotid vasculature.

SUBSTANTIAL EQUIVALENCE

The subject Pantheris System and the primary predicate device, the current Pantheris System (cleared under K160827) are identical. They have the same device specifications, materials, manufacturing processes, device packaging, principles of operation for vessel visualization and OCT technological characteristics. Post the clearance of K160827 on March 1, 2016, the current Pantheris System's Lightbox software was updated to version 4.0.1. The proposed Indications for Use for the subject Pantheris System is very similar to the current Pantheris System (K160827) Indications for Use.

The subject Pantheris System and the secondary predicate device, the initial Pantheris System (cleared under K152275) are very similar. They have almost identical device specifications, materials, manufacturing processes, device packaging, principles of operation for vessel visualization and OCT technological characteristics.

The subject Pantheris System and the secondary predicate device, the Ocelot System (K140185) have very similar intended use, principles of operation for vessel visualization and OCT technological characteristics.

Any differences between the subject Pantheris System and the predicate devices do not alter the intended use or impact the safety and effectiveness of the Pantheris System.

NONCLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

The subject Pantheris System is identical to the primary predicate device, the Pantheris System cleared under K160827. The changes proposed in this submission do not alter the Pantheris System specifications, design, functionality or manufacturing process. The changes only pertain to updates to the labeling to accurately reflect the Pantheris System's current imaging functionality.

The non-clinical, bench testing conducted on the Pantheris System and provided in the prior K160827 and K152275 submissions, are applicable to the subject Pantheris System, including the following:

- Design verification and bench validation studies
- Packaging and shelf-life
- Software verification and validation
- Electrical safety, electromagnetic compatibility, and laser safety testing
- Biocompatibility
- In-vivo animal validation study
- Sterilization

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

Use of the same OCT technology between the subject and the predicate devices, along with successful OCT image comparisons between the subject Pantheris System, the Ocelot System (K140185) and images from the submitted compendium, confirm a determination of substantial equivalence between the subject device and the predicate devices regarding the updates to the subject Pantheris System labeling.

CLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

Clinical testing of the Pantheris System was included for the secondary predicate, the initial Pantheris System original 510(k) submission (K152275). Due to the equivalence between the Systems no new clinical testing is included in this 510(k) submission.

CONCLUSION

The subject Pantheris System discussed in this submission is equivalent to the primary predicate device (current Pantheris System, K160827) in terms of specifications, design, functionality and manufacturing process. No new issues of safety or effectiveness are raised in this submission. The use of identical OCT technology in the predicate devices (the current Pantheris System (K160827), the intial Pantheris System (K152275) and the Ocelot System (K140185) and the successful OCT image comparisons, confirm that the Pantheris System is substantially equivalent to the predicate devices listed above.