DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 1, 2016

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

Re: K153460
Trade/Device Name: Pantheris System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: January 27, 2016
Received: January 28, 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 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)*
K153460

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 7.0 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.

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

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510(k) Summary

510(k) Notification K 153460

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
VP, Clinical and Regulatory Affairs
Avinger, Inc.
Phone: 650-222-3666
Email: phevey@avinger.com

Date Prepared:

November 30th, 2015

DEVICE INFORMATION

Trade Name:

Pantheris System

Generic/Common Name:

Peripheral Atherectomy Catheter

Classification:

21 CFR§870.4875, Intraluminal Artery Stripper, Class II

Product Codes:

MCW

PREDICATE DEVICES

The modified *Pantheris Catheter* is substantially equivalent to the original *Pantheris Catheter* cleared under K152275.

DEVICE DESCRIPTION

The Pantheris System recently received clearance under K152275 to remove plaque (atherectomy) from partially occluded vessels in the peripheral vasculature using OCT-assisted orientation. The Pantheris Catheter reviewed as part of K152275 has since been modified to help improve manufacturability and usability of the catheter. The Pantheris System consists of the Pantheris Catheter, Lightbox Sled (referred to as Sled), the Lightbox HS Imaging Console and the Sterile Drape (accessory).

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 7.0 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 modified Pantheris Catheter is essentially the same device as the original Pantheris Catheter cleared under K152275; both share the same basic design, principles of operations, mechanism of action and indications for use. Any differences between the modified Pantheris Catheter and the original Pantheris Catheter do not alter the intended use of the Pantheris System. The modifications made to the original Pantheris Catheter (K152275) to create the proposed device are provided in Table 1 below. The information included in this submission will establish the substantial equivalency of the modified Pantheris Catheter to the original Pantheris Catheter cleared under K152275.

Table 1: Modified Pantheris Catheter Changes

Catheter Section	Design Modifications
Distal Assembly	• Offering a 7Fr catheter option • Modifying the shape of the Apposition Balloon • Including additional viewing windows and increasing the length of the Nosecone Housing • Replacing the flush channel with vent holes
Torque Shaft Assembly	• Reducing the working length from 130cm to 110cm • Relocating the Occlusion Balloon to the Torque Shaft (thereby obsoleting the optional accessory, Occlusion Sheath) • Increasing the Torque Shaft stiffness
Handle Assembly	• Improving the ergonomics of the handle design • Extending the blue color coding across the entire Flush Lumen length
Packaged Accessories	• Replacing 1mL Syringe with 6mL and 10mL Syringes

NON-CLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

To demonstrate the substantial equivalences of the Pantheris Catheter to the selected predicate device, the performance and technological characteristics were evaluated by completion of the following testing:

- Design Verification
  - Working Length
  - Catheter Flush
  - OCT Image Generation and Sled Interface
  - Catheter Field of View
  - Distal Tip Rotation
  - Guidewire compatibility
  - Distal Tip Max OD
  - Insertion Force
  - Force to Overcome User Slide Lock
  - Force to Remove Sled Bag
  - Force to Remove Sled Bag ring
  - Full 360° Image
  - Inflation Cycles
  - Cut/Pack Cycles
  - Packed Position Life Cycle
  - Active position Life Cycle
  - Balloon Burst

  - Torque Shaft Torque Proof loading
  - Drive Shaft Torque Proof loading
  - Inflation Luer Tensile Strength
  - Flush lumen Tensile Strength
  - Distal Catheter Joints Tensile Strength
  - Proximal Catheter Joints Tensile Strength
- Simulated Use (Design Validation)
  - Setup (Ease of Use & Sterility)
  - Functionality (Visualization, Flushing, Device Tracking, Target Sites, Treatment, Markings, Safety)
  - Insertion/Retraction force
  - Number of Insertions
  - Post-Retraction (Visualization, Device Tracking, Treatment, Markings, Safety)
- Sterilization Validation
- Packaging Validation
- Product Shelf Life
- Biocompatibility
  - Cytotoxicity
  - Sensitization
  - Intracutaneous Reactivity
  - Systemic Toxicity
  - Hemolysis – extract
  - Hemolysis – direct
  - Complement Activation
  - Material Mediated (Rabbit) Pyrogenicity
- Preclinical Animal Testing
  - Porcine Study with acute and chronic histopathological assessments and in vivo performance comparison to a predicate device, with 8F Pantheris catheter
  - Functionality
    - Radiopacity
    - OCT marker visibility
    - Insertion/Retraction
    - Advance to target location
    - Ability to orient device to a landmark
  - Minimum Effective Flow Rate (MEFR) for clear OCT imaging
  - Thrombogenicity
  - Safety Assessment

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

CONCLUSION

The modified Pantheris Catheter has been carefully compared to the original Pantheris Catheter device with respect to intended use and fundamental technological characteristics. Performance testing was conducted to verify and validate the performance of the devices and ensure the modified Pantheris Catheter functions as intended and meet design specifications. The comparison and performance testing results demonstrate that the modified Pantheris Catheter is substantially equivalent to the original Catheter cleared under K152275 for the stated intended use.