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

April 21, 2016

Avinger, Inc.
Ms. Golnaz Moeini
Senior Regulatory Affairs Specialist
400 Chesapeake Drive
Redwood City, California 94063

Re: K160827
Trade/Device Name: Pantheris Catheter
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: March 24, 2016
Received: March 25, 2016

Dear Ms. Moeini:

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)*
K160827

Device Name
Pantheris Catheter

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.

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510(k) Summary

General Information

510(k) Sponsor	Avinger, Inc.
Address	400 Chesapeake Drive Redwood City, CA 94063
FDA Registration Number	3007498664
Correspondence Person	Golnaz Moeini Sr. Regulatory Affairs Specialist Avinger Inc.
Contact Information	Email: gmoeini@avinger.com Phone: 408-504-3187
Date Prepared	March 23rd, 2016

Proposed Device

Proprietary Name	Avinger Pantheris Accessories
Common Name	Avinger Pantheris Catheter
Classification Name	Intraluminal Artery Stripper
Regulation Number	21 CFR§870.4875
Product Code	MCW
Regulatory Class	II

Predicate Device

Proprietary Name	Avinger Pantheris Catheter (K153460)
Premarket Notification	K153460
Classification Name	Intraluminal Artery Stripper
Regulation Number	21 CFR§870.4875
Product Code	MCW
Regulatory Class	II

Device Description

The Pantheris Catheter received clearance under K153460 to remove plaque (atherectomy) from partially occluded vessels in the peripheral vasculature using OCT-assisted orientation. This Special 510(k) submission is intended to add Tweezers and two 3-way Stopcocks to the Pantheris Catheter packaging. The Tweezers are provided to assist in the extraction of tissue that is collected during the atherectomy procedure from the distal end of the catheter once the catheter is removed from the patient. The catheter can then be re-inserted into the vessel to continue plaque removal using the

same technique. The Tweezers are not intended to come into direct contact with the patient.

The Stopcocks are standard, off the shelf accessories, used to facilitate the delivery of CO_2 and saline to the catheter. The Syringes are connected to the Flush and Balloon Inflation Lumens (components on the catheter's handle assembly) via the Stopcocks. The Stopcocks are not intended to come into direct contact with the patient.

Both the Tweezers and the Stopcocks are provided in order to make readily available these commonly used accessories and for user's convenience.

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.

Comparison of Technological Characteristics with the Predicate Device

The cleared Pantheris Catheter package includes the catheter, a flush fixture and 6mL and 10mL Syringes. Avinger is proposing to add Tweezers and two 3-way Stopcocks to the Pantheris Catheter packaging. There are no modifications to the indications for use, intended use, material, design, functionality or performance of the catheter, flush fixture and syringes cleared under K153460. The Tweezers and Stopcocks are provided for user convenience purposes. The performance testing conducted establishes that the addition of Tweezers and Stopcocks does not raise new questions of the safety and efficacy for the Pantheris Catheter cleared under K153460.

Non-Clinical Test Data

Tweezers and Stopcocks used in conjunction with the Pantheris Catheter has been evaluated in accordance with design specifications and applicable performance standards through biocompatibility assessment, packaging, sterilization and shelf life validation.

The Pantheris Catheter design, performance, material, indications for use and fundamental technology are identical to the cleared Pantheris Catheter (K153460), supporting a determination of substantial equivalence.

The biocompatability of the Tweezers and Stopcocks were verified per *ISO10993-1:2009 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process and related collateral standards for patient contacting materials* (see *Section 13.3, Biocompatibility*).

The packaging and shelf-life validation were performed to test the packaging tray configuration in accordance to *ISO 11607-1:2006 Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems* and *ISO 11607-2:2006, Packaging for terminally sterilized medical devices- Part 2: Validation requirements for forming, sealing and assembly process*

The Pantheris Catheter along with accessories is provided sterile and utilizes the same sterilization process as the cleared device. The sterilization validation was repeated to verify the product maintain the Sterility Assurance Level of 10^{-6} using Electron Beam sterilization per Method VD_{Max}^{25} in accordance with *ISO 11137-1:2006, Sterilization of health care products- Radiation, Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* and *ISO 11137-2:2006 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose.*

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

Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics, performance testing and material comparison to the predicate device, the Pantheris accessories raise no new questions of safety and effectiveness and the device is substantially equivalent to the predicate device.