DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

December 21, 2016

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

Re: K163264
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: November 17, 2016
Received: November 21, 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)*
K163264

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.

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SECTION 7. 510(k) Summary

General Information

510(k) Sponsor	Avinger, Inc.
Address	400 Chesapeake Drive Redwood City, CA 94063
FDA Registration Number	3007498664
Correspondence Person	Patty Hevey V.P. Clinical and Regulatory Affairs Avinger Inc.
Contact Information	Email: phevey@avinger.com Phone: 650-222- 3666
Date Prepared	Nov 15th, 2016

Proposed Device

Trade Name	Pantheris System
Common Name	Avinger Pantheris Catheter
Regulation Number and Classification Name	21 CFR§870.4875, Intraluminal Artery Stripper 21 CFR§892.1560, Ultrasonic Pulsed Echo Imaging System
Product Code	MCW, NQQ
Regulatory Class	II

Predicate Device

Trade Name	Pantheris System
Common Name	Avinger Pantheris Catheter
Premarket Notification	K162326
Regulation Number and Classification Name	21 CFR§870.4875, Intraluminal Artery Stripper 21 CFR§892.1560, Ultrasonic Pulsed Echo Imaging System
Product Code	MCW, NQQ
Regulatory Class	II

Device Description and Proposed Modification

The Pantheris System (cleared under K162326) combines the use of Avinger's Optical Coherence Tomography (OCT) technology with peripheral vascular atherectomy capabilities. The Pantheris System consists of the Pantheris Catheter, Lightbox Sled with integrated Umbilical (referred to as "Sled") and the Lightbox HS Imaging Console (referred to as "Lightbox").

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, software, an isolation transformer and an OCT system.

This Special 510(k) introduces an optional vessel measurement feature to the Pantheris System software in the Lightbox HS Imaging Console.

Prior to or post atherectomy procedures, physicians routinely use fluoroscopy to make visual assessments of the vessel diameter and size. This helps decide the device sizing of their choice for treatment, post atherectomy (*e.g.* balloon or stenting after atherectomy). The vessel measurement feature that is being introduced via this Special 510(k) submission is only intended to be used by the physicians as an optional confirmation of their initial vessel diameter/size assessment.

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 as 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.

Comparison of Technological Characteristics with the Predicate Device

This minor modification to the Pantheris System software (cleared under K162326) does not alter the intended use or the fundamental scientific technology of the Pantheris system. There is also no change to the design, functionality, performance, materials or manufacturing processes of the Pantheris System components or accessories as part of this Special 510(k) submission. The modified software does not offer any therapy or treatment recommendations; it only serves to provide an option to the physician if they want additional information to confirm their initial vessel size assessment.

The performance testing conducted establishes that the minor software modification of including an optional measurement feature does not raise new questions of the safety and efficacy for the Pantheris System cleared under K162326.

Non-Clinical Test Data

The minor modification to the Pantheris System software to include the optional measurement feature was successfully verified to the specifications and all acceptance criteria were met. In addition, the accuracy of the measurement feature was assessed and found to be within the specified acceptance criteria.

By design the vessel measurement feature is segregated from the active live OCT imaging software, therefore this minor modification to the software does not impact any of the Pantheris System's existing functionality.

Conclusion

The information submitted in this premarket notification, including the successful completion of software verification and measurement accuracy testing, confirms that the minor modification to the Pantheris System software raises no new questions of safety and effectiveness and the device is substantially equivalent to the predicate device.