October 30, 2017

Avinger, Inc.
Thomas Lawson
Director, Regulatory and Clinical Affairs
400 Chesapeake Drive
Redwood City, California 94063

Re: K172236
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: September 29, 2017
Received: October 2, 2017

Dear Mr. Lawson:

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 (DICE) 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 (DICE) 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,

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)*
K172236

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 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.

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# 510(k) Summary

## General Information

| | |
|---|---|
| Submitter | Avinger, Inc. |
| Address | 400 Chesapeake Drive<br>Redwood City, CA 94063 |
| FDA Registration Number | 3007498664 |
| Correspondence Person | Thomas Lawson, PhD<br>Director, Clinical & Regulatory Affairs<br>Avinger Inc. |
| Contact Information | Email: tlawson@avinger.com<br>Phone: 510-206-1794 |
| Date Prepared | 29 September 2017 |

## Proposed Device

| | |
|---|---|
| Trade Name | Pantheris System |
| Common Name | Avinger Pantheris Catheter |
| Regulation Number and Classification Name | 21 CFR§870.4875, Intraluminal Artery Stripper<br>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<br>21 CFR§892.1560, Ultrasonic Pulsed Echo Imaging System |
| Product Code | MCW, NQQ |
| Regulatory Class | II |
| Note: This predicate device has not been subject to a design-related recall. | |

## Device Description and Proposed Modifications

The Pantheris System (cleared initially under K152275) 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 comes in both a 7Fr and an 8Fr size. Both sizes have a working length of 110 cm and are sterile, single-use devices that are compatible with 7 and 8F 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, software, an isolation transformer, and an OCT system.

The Pantheris catheter is to be used in a healthcare facility, such as a cardiac catheter lab or a hospital. It is to be used and in contact with patient tissue for less than 24 hours and is made of materials that are biocompatible.

The submission of K162326 for the Pantheris system was focused solely on a change in the system software that permits the use of OCT images to identify vessel lumen, wall structures, and vessel morphologies.

This Special 510(k) details modifications to improve manufacturing compatibility, modify accessories that have no direct patient contact, and describes a patch of the system software that allows the attenuation of the laser whenever the drive in the Sled is not rotating.

**Indications for Use**

The indications for use for the Pantheris System cleared under K163264 is not altered due to the software and other modifications disclosed in this submission:

> 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 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.

Both the subject device and the predicate device have the same intended use for the removal of plaque from partially occluded vessels in the peripheral vasculature.

**Comparison of Technological Characteristics with the Predicate Device**

Excision of plaque from peripheral vessels through atherectomy is the technological principle for both the subject and predicate devices.

At a high level, the subject and predicate devices are based upon the same technological elements:

- Device is advanced to the point of treatment through an indwelling sheath;
- Measurement and display of vessel lumen, wall structures, and vessel morphology via the OCT-imaging component located directly behind the tissue cutter component;
- Rotation of the OCT-imaging and cutter components by drives in the Sled component of the system;
- Display of OCT-generated images on monitors attached to the Lightbox component of the system;
- Excision of targeted tissue by a cutter component; and
- Packing of excised tissue into the nosecone component of the catheter.

The only technological difference is that the patch release of the software in the subject device allows the attenuation of the laser whenever the drive in the Sled is not rotating. In the predicate device, the laser is not stopped when the drive is not rotating.

Summary of Technological Characteristics of the Subject Device Compared to Those of the Predicate Device

| Technological Characteristic | Pantheris Catheter Predicate Device K162326 | Pantheris Catheter Subject Device of this Submission |
|---|---|---|
| Indication 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 and imaging. The system is as an adjunct to fluoroscopy by providing images of vessel | Same |

| | | |
|---|---|---|
| | lumen, wall structures and vessel morphologies.<br><br>The Pantheris System **is NOT** intended for use in the iliac, coronary, cerebral, renal or carotid vasculature.” | Same |
| Anatomical Site of Use | Peripheral Vasculature | Same |
| Components of the System | Lightbox console<br>Sled<br>Pantheris Catheter | Same |
| Imaging Modality | Optical Coherence Tomography | Same |
| Imaging Energy Type | Near-infrared light | Same |
| Optical Output Power | < 30 mW<br>(Class 1M laser output) | Same |
| Optical sensitivity (signal:noise ratio) | 90 db minimum | Same |
| Attenuation of the laser when the Sled driver is not rotating | No | Yes |
| Imaging Capabilities | OCT-assisted orientation and imaging of vessel lumen and wall structures in the peripheral vasculature to facilitate atherectomy.<br><br>Identify clinically relevant morphologies and assess complex lesions in the peripheral vasculature.<br><br>Differentiate and classify plaque | Same<br><br>Same<br><br>Same |
| Electrical Safety | Class I, Type CF, defibrillation proof<br>IEC 60601-1 | Same |
| Electromagnetic compatibility | IEC 60601-1-2 | Same |
| Laser Safety | 21 CFR Part 1040<br>IEC 60825 | Same |
| Software Level of Concern | Moderate | Same |

| | | |
|---|---|---|
| Sheath compatibility for the catheter | 7 Fr & 8 Fr | Same |
| Working length of the catheter | 110 cm | Same |
| Guidewire compatibility of the catheter | 0.014 in | Same |
| Distal tip OD of the catheter | 0.100 (7 Fr)<br>0.110 (8 Fr) | Same<br>Same |
| Provided Sterile | Yes | Yes |
| Single-use catheter | Yes | Yes |

While the technique of plaque excision between the subject and predicate devices are the same, there have been design changes to the subject device to improve manufacturability and usability of the catheter, changes to the tweezers and flush fixture accessories, modification of the Sled component of the system, updates to the instructions for use, and a patch release of the system's software. The design changes are summarized below.

Summary of design and other changes of the subject device covered in this 510(k) submission:

Manufacturing

- Modify balloon inflation test during assembly
- Shorten the torque shaft hypotube length
- Add strain relief in the handle to reduce tension pulling on fibers from the lens
- Modify the edge of the cutter
- Modify the bushing that aligns the cutter

Sled

- Modify the integrated connector of the umbilical cable
- Modify the FORJ, which increased the length of the Sled slightly

Accessories

- Change tweezers material from nylon to stainless steel and change the shape of its tip
- Length the flush fixture increased

Labeling

- Revise the IFU in terms of volume of CO2 used to inflate the balloons
- Revise the IFU to instruct user to test balloon inflation prior to insertion of the catheter

Software

- Update of software to allow attenuation of the laser whenever the drive in the Sled is not rotating

Testing was performed to demonstrate that these changes do not impact the safety and effectiveness of the final device.

**Performance Data**

The performance testing conducted establishes that these minor modifications do not raise new questions of the safety and effectiveness for the Pantheris System cleared under K163264.

**Biocompatibility testing**

There are no changes in patient-contacting materials in the subject device when compared to the predicate device. The only material change is to an accessory provided with the device, a pair of tweezers, which were nylon in the predicate device and in the subject device are stainless steel. The stainless steel tweezers do not have direct patient contact, but were subjected nonetheless to the following testing and passed all tests:

- Cytotoxicity;
- Sensitization;
- Irritation; and
- Systemic toxicity.

**Electrical safety and electromagnetic compatibility (EMC)**

The predicate and subject devices comply with IEC 60601-1 standard for safety and the IEC 60601-1-2 standard for EMC.

**Software Verification and Validation Testing**

Software verification and validation testing, as well as regression testing, were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*. The software for this device is considered as a "moderate" level of concern.

**Mechanical Testing**

The mechanical testing of the subject device included:

- Sheath insertion cycle test;
- Destructive balloon burst test;

- Torque capacity;
- Leak evaluation;
- Bond joint tensile strength;
- Life-cycle tests;
- 8-month accelerated shelf life study;
- Simulated use testing;
- Corrosion testing*;
- Heat generation testing;
- Rotational speed testing*;
- Dimensional verification*;
- Balloon inflation/deflation cycle test;
- Plaque removal efficiency; and
- Flushing tool capacity.

*device historical data/information was provided to support the test conclusions

**Animal Testing**

No preclinical testing of the modifications of the subject device was necessary.

**Clinical Studies**

No clinical testing of the modifications of the subject device was necessary.

**Conclusion**

The information submitted in this premarket notification confirms that the minor modifications to the Pantheris catheter, components, and system software raise no new questions of safety and effectiveness and that the device is substantially equivalent to the predicate device.