June 6, 2023

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

Re: K230005
Trade/Device Name: Pantheris LV Atherectomy Catheter
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal artery stripper
Regulatory Class: Class II
Product Code: MCW, NQQ
Dated: May 2, 2023
Received: May 4, 2023

Dear Thomas 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Eleni Whatley -S Digitally signed by Eleni Whatley -S Date: 2023.06.06 12:56:40 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230005

Device Name
Pantheris LV Atheterctomy Catheter

Indications for Use *(Describe)*

The Pantheris LV System is indicated to remove plaque (atherectomy) from partially occluded native or restenotic vessels, including in-stent restenosis (ISR), 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 LV 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 Redwood City, CA 94063
FDA Registration Number	3007498664
Correspondence Person	Thomas Lawson, PhD VP, Clinical & Regulatory Affairs Avinger Inc.
Contact Information	Email: tlawson@avinger.com Phone: 510-206-1794
Date Prepared	5 June 2023

Proposed Device

Trade Name	Pantheris LV Atherectomy Catheter
Common Name	Pantheris LV
Regulation Number and Classification Name	21 CFR§870.4875, Intraluminal Artery Stripper 21 CFR§892.1560, Imaging System Optical Coherence Tomography (OCT)
Product Code	MCW, NQQ
Regulatory Class	II
NOTE: This is the first 510(k) submission for this device.	

Primary Predicate Device

Trade Name	Pantheris SV Atherectomy Catheter
Common Name	Pantheris
Premarket Notification	K201330
Regulation Number and Classification Name	21 CFR§870.4875, Intraluminal Artery Stripper 21 CFR§892.1560, Imaging System Optical Coherence Tomography (OCT)
Product Code	MCW, NQQ
Regulatory Class	II
Note: This predicate device has not been subject to a design-related recall.	

Reference Device

Trade Name	Pantheris Atherectomy Catheter
Common Name	Pantheris
Premarket Notification	K173862 & K212047
Regulation Number and Classification Name	21 CFR§870.4875, Intraluminal Artery Stripper 21 CFR§892.1560, Imaging System Optical Coherence Tomography (OCT)
Product Code	MCW, NQQ
Regulatory Class	II
Note: This reference device has not been subject to a design-related recall.	

Device Description and Proposed Modifications

The Pantheris LV catheter combines the use of Avinger's optical coherence tomography (OCT) technology with peripheral vascular atherectomy capabilities. The Pantheris LV System consists of the Pantheris LV catheter, a Lightbox Sled with integrated umbilical (referred to as "Sled"), and the Lightbox Imaging Console (referred to as "Lightbox").

The subject device of this submission is a product line extension of the Pantheris SV System reviewed and cleared earlier under K182341.

The Pantheris LV catheter is a 7 French device with a working length of 110 cm. It is comprised of two components—an outer support catheter and an inner assembly or drive shaft. It is provided sterile and is a single-use device compatible with 5 Fr vascular sheaths. The Pantheris LV catheter incorporates an optical fiber that allows real-time diagnosis of vessel condition and morphology as well as OCT-guided atherectomy during the procedure with its connection to the Lightbox.

The Pantheris LV 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.

This Traditional 510(k) builds on the Pantheris SV (K182341) and Pantheris v1.4 (K173862) atherectomy catheter designs and details additional minor modifications to the design of the Pantheris catheter family to add in functionality of the device.

Indications for Use

The indication for use for the Pantheris LV catheter is:

> The Pantheris LV System is intended to remove plaque (atherectomy) from partially occluded native or restenotic vessels, including in-stent restenosis (ISR), 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 LV System is NOT intended for use in the iliac, coronary, cerebral, renal or carotid vasculature.

Both the subject device and the reference device have the same intended use of debulking plaque in the lumen of peripheral arteries sized 3 to 7 mm in diameter. The subject device and predicate device are made from the same materials and use the same packaging.

Comparison of Technological Characteristics with the Predicate and Reference Devices

Avinger Inc. has identified the Pantheris SV catheter (K182341) as the predicate device and the Pantheris v1.4 (K173862) catheter as the reference device for the Pantheris LV catheter.

The Pantheris LV catheter is substantially equivalent to the predicate device with its design of a jog in the distal segment of the cannula that results in the cutter contacting target tissue as is the design of the Pantheris SV catheter. The Pantheris LV catheter is substantially equivalent to the Pantheris v1.4 catheter in its outer diameter (7 Fr) and indications of use in peripheral vessels 3 to 7 mm in diameter.

The Pantheris LV catheter is substantially equivalent to the predicate and reference devices in its clinical utility based upon the following factors:

- The three devices are intended to be used to debulk lesions disrupting and restricting blood flow in peripheral vessels.
- The three devices are used in cardiac catheter labs in either a hospital or an office-based lab.
- The three devices are advanced to the target lesion through an indwelling vascular sheath.
- Advancement of the three devices is monitored by external fluoroscopy and the catheters' on-board intravascular OCT imaging component.
- The three devices consist of a rotating cutter that actively engages the plaque

tissue causing removal of the occlusive tissue and a power source to cause the device rotation of the cutter and display the OCT image during the procedure.

Comparison of the Pantheris LV catheter to the Pantheris SV catheter (predicate device), and the Pantheris v1.4 catheter (reference device).

	Predicate Device Pantheris SV System (Avinger, Inc.) K182341	Reference Device Pantheris System (Avinger, Inc.) K173862 & K212047	Subject Device Pantheris LV System (Avinger, Inc.) (This Submission)
Indication for Use	The Pantheris SV catheter is intended to remove plaque (atherectomy) from partially occluded vessels in the peripheral vasculature with a reference diameter of 2.0 mm to 4.0 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 SV System is NOT intended for use in the iliac, coronary, cerebral, renal or carotid vasculature.	The Pantheris System is intended to remove plaque (atherectomy) from partially occluded native or restenotic vessels, including in-stent restenosis (ISR), 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.	Identical to the Pantheris v1.4 catheter
Intended use	Remove plaque (atherectomy) from partially occluded peripheral arteries	Identical	Identical
Contraindications	The Pantheris SV System is contraindicated for use in the iliac, coronary,	Identical	Identical

	cerebral, renal or carotid vasculature.		
Product Code	MCW & NQQ	Identical	Identical
Treatment Method	Debulking of plaque within the lumen of peripheral arteries	Identical	Identical
Technical Characteristics			
Components of the System	Catheter Lightbox Imaging Console Sled	Identical	Identical
Imaging Modality	Optical coherence tomography	Identical	Identical
Imaging Energy Type	Near-infrared Light	Identical	Identical
Optical Output Power	< 30 mW (Class 1 laser)	Identical	Identical
Optical Sensitivity (signal : noise ratio)	90 db minimum	Identical	Identical
Imaging Capabilities	OCT-assisted orientation and imaging of vessel lumen and wall structures in the peripheral vasculature to facilitate crossing of vessel occlusions. Measurement of vessel lumen by OCT	Identical Identical	Identical Identical
Electrical Safety	Class I, Type CF, defibrillation proof IEC 60601-1	Identical	Identical
Electromagnetic Compatibility	IEC 60601-1-2	Identical	Identical
Laser Safety	21 CFR Part 1040 IEC 60825	Identical	Identical
Software Level of Concern	Moderate	Identical	Identical
Sterilization Method	e-beam irradiation	Identical	Identical
Sterility Assurance Level	10^{-6}	Identical	Identical
Biocompatibility of Materials	Meets ISO 10993 requirements	Identical	Identical

Operational Characteristics			
Outer diameter of the cannula	2 mm (6 Fr)	2.3 mm (7 Fr)	2.3 mm (7 Fr)
Tip length	4 cm	6 cm	6 cm
Working length of the catheter	140 cm	110 cm	110 cm
Sheath compatibility for the catheter	6 Fr	7 Fr	7 Fr
OCT imaging sweep/window	360 degrees	Identical	Identical
Mechanism performing atherectomy	Cutting assembly comprised of a rotating inner blade contained within a tubular housing	Identical	Identical
Guidewire compatibility	0.014 inch	Identical	Identical
Procedure Site	Hospital Cardiac Catheter Lab Office-based Lab	Identical	Identical
Anatomical Site of Use	Peripheral Vasculature	Identical	Identical
Reference vessel diameter	2 to 4 mm	3 to 7 mm	3 to 7 mm
Treatment Method	The cutting blade "shaves" plaque from the vessel wall and captures it in the nosecone of the device. Cutting sequence is repeated as necessary to achieve the desired degree of plaque excision	Identical Identical	Identical Identical
Provided Sterile	Yes	Yes	Yes
Single-use catheter	Yes	Yes	Yes

Performance Data

The performance testing conducted establishes that the Pantheris LV catheter did not raise new questions of the safety and effectiveness from those reviewed and cleared in the previous atherectomy catheter submissions K182341 and K173862.

Biocompatibility testing

The Pantheris LV catheter is manufactured from materials with a long history in medical devices and that are used in the Pantheris SV catheter (K182341), which were tested under 10993-1. As a result, the full biocompatibility suite of tests is not necessary; however, the Pantheris LV catheter was assessed with the cytotoxicity test and found to be non-cytotoxic.

Electrical safety and electromagnetic compatibility (EMC)

The subject and predicate devices comply with IEC 60601-1 standard for safety and the IEC 60601-1-2 standard for EMC, as reviewed in K182341 (for the L250 console) and K212468 (for the L300 console).

Mechanical Testing

The mechanical testing of the subject device included:

- Simulated use testing
- Working length test
- Catheter flush and leak test (following BS EN 1707:1997)
- OCT image generation and Sled interface test
- Catheter field of view test
- Distal tip rotation test
- Guidewire compatibility and insertion force test
- Catheter-Sheath insertion cycles test
- Insertion force through the hub test
- Retraction force through the hub test
- Insertion force over the arch test
- Insertion force out of the sheath test
- Cutter exposure test
- OCT image generation and Sled interface test
- Full 360º image test
- Cut/Pack cycles test
- Catheter Sled insertion cycles test
- Packed position life cycle test
- Active position life cycle test
- Torque shaft torque—proof loading test
- Driveshaft torque—proof loading test
- Guidewire lumen peel strength—proof loading test

- Proximal section torque shaft torque test
- Flush lumen luer tensile strength test (following ISO 10555-1:2013)
- Distal catheter joints tensile strength test (following ISO 10555-1:2013)
- Proximal catheter joints tensile strength test (following ISO 10555-1:2013).

Animal Testing

Preclinical (animal) testing of the subject device was not necessary. The testing that was completed was sufficient to demonstrate substantial equivalence of this model of Avinger's atherectomy catheters.

Clinical Studies

Clinical testing of the subject device was not necessary. The testing that was completed was sufficient to demonstrate substantial equivalence of this model of Avinger's atherectomy catheters.

Conclusion

The information submitted in this premarket notification confirms that the extension of the Pantheris Family of Atherectomy Catheters to now include the Pantheris LV catheter raises no new questions of safety and effectiveness and that the Pantheris LV catheter is substantially equivalent to the predicate device.