November 16, 2021

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

Re: K212047
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: October 6, 2021
Received: October 8, 2021

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,

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)*
K212047

Device Name
Pantheris System

Indications for Use *(Describe)*

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.

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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K212047

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 Director, Clinical & Regulatory Affairs Avinger Inc.
Contact Information	Email: tlawson@avinger.com Phone: 510-206-1794
Date Prepared	16 November 2021

Proposed Device

Trade Name	Pantheris System
Common Name	Pantheris Catheter
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

Predicate Device #1—Primary Predicate Device

Trade Name	B-Laser Atherectomy System
Common Name	B-Laser
Premarket Notification	K181642
Regulation Number and Classification Name	21 CFR§870.4875, Intraluminal Artery Stripper
Product Code	MCW
Regulatory Class	II
Note: This predicate device has not been subject to a design-related recall.	

Predicate Device #2—Reference Predicate Device

Trade Name	Pantheris System
Common Name	Pantheris Catheter
Premarket Notification	K173862
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
Regulatory Class	II
Note: This predicate device has not been subject to a design-related recall.	

Device Description and Proposed Modifications

The Pantheris System consists of a Pantheris atherectomy catheter, a Lightbox Sled with integrated umbilical (referred to as "Sled"), and a Lightbox HS Imaging Console (referred to as "Lightbox"). The Pantheris atherectomy catheter is a 7 French device with a working length of 110 cm. It 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 via the Sled accessory.

The Pantheris System was reviewed and cleared under K173862. Neither the catheter, the Sled, nor the Lightbox were modified for use in the clinical trial conducted to support this submission and all three elements of the system are the same as they were when cleared under K173862.

This Traditional 510(k) is submitted in order to expand the indications for use statement to include in-stent restenosis as a condition for use of the Pantheris catheter.

Proposed Indications for Use Statement

The indication for use for Pantheris atherectomy catheter cleared in K173862 is to be modified to include restenotic vessels, including in-stent restenosis (ISR):

> 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.

Equivalence of the Subject Device with the Two Predicate Devices

Avinger Inc. has identified the B-Laser Atherectomy System (K181642) as the primary predicate device due to a shared indication to address in-stent restenosis.

The Pantheris catheter is substantially equivalent to the B-Laser Atherectomy System based upon the following similarities:

- Both devices are intended to be used to address in-stent restenosis in peripheral vessels by atherectomy, under product code MCW;
- Both devices are used in cardiac catheter labs in either a hospital or an office-based lab;
- Both devices are advanced to the target in-stent occlusion through an indwelling vascular sheath and over a guide wire;
- Advancement to the target tissue for both devices is monitored by external fluoroscopy imaging; and
- Both devices have equivalent sizes in terms of outer diameter and working length of the catheter.

The Pantheris 7Fr catheter (subject device) and Pantheris 7Fr catheter (reference predicate device) cleared under K173862 are the exact same device. This predicate device covers specifications, materials, biocompatibility, sterilization, and packaging for the device used in the IDE trial to gather clinical data for ISR treatment.

Table 14.1 shows the comparison of the Pantheris 7 Fr catheter to the predicate devices. The equivalences among these three devices satisfy the criteria for a 510(k) submission.

Table 14.1 Comparison of the Pantheris 7Fr catheter (subject device) to the predicate devices, the Laser-B atherectomy catheter (K181642) and the Pantheris 7Fr catheter (K173862).

	Subject Device Pantheris Atherectomy System 7 French (Avinger, Inc.) (This Submission)	Primary Predicate Device B-Laser Atherectomy System (Eximo Medical Ltd.) K181642	Reference Predicate Device Pantheris Atherectomy System 7 French (Avinger, Inc) K173862
Overview			
Class	II	II	II
Product Code	MCW NQQ	MCW	MCW NQQ
Classification Section	21 CFR §870.4875 Intraluminal Artery Stripper	Same	Same
Indication for Use	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 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,	The B-Laser Atherectomy System is intended for use in the treatment, including atherectomy, of infra-inguinal stenoses and occlusions, including in-stent restenosis (ISR).	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 lumen, wall structures and vessel morphologies. The Pantheris System is NOT intended for use in the iliac, coronary, cerebral, renal or carotid

	coronary, cerebral, renal or carotid vasculature.		vasculature.
Intended use	Remove plaque (atherectomy) from partially occluded native or restenotic vessels, including in-stent restenosis (ISR), in the peripheral vasculature	Remove plaque (atherectomy) from partially occluded vessels in the peripheral vasculature, including in-stent restenosis	Remove plaque (atherectomy) from partially occluded vessels in the peripheral vasculature
Treatment Method	Atherectomy using a rotating cutter head	Atherectomy with an array of optic fibers surrounded by a circumferential blunt blade	Atherectomy using a rotating cutter head
Technical Characteristics			
Design	System is comprised of (1) catheter, (2) imaging console, and (3) connector between the catheter and the console	System is comprised of (1) catheter, (2) laser console, and (3) connector between the catheter and the console	System is comprised of (1) catheter, (2) imaging console, and (3) connector between the catheter and the console
Configuration of the Catheter	A cannula that contains a rotating cutter head and an OCT imaging fiber	A cannula that contains an array of optic fibers surrounded by a circumferential blunt blade	A cannula that contains a rotating cutter head and an OCT imaging fiber
Outer Diameter of the Catheter	2.3 mm (7Fr)	2.0 and 2.35 mm (6 & X Fr)	2.3 mm (7 Fr)
Working Length of the Catheter	110 cm	125 to 150 cm	110 cm
Mechanism of Tissue Excision	Rotating cutter head that cuts the target tissue	Laser pulses for photoablation of the target tissue	Rotating cutter head that cuts the target tissue
Excised Tissue Management	Excised tissue is collected and contained in an integrated storage	Excised tissue is collected and removed using vacuum aspiration	Excised tissue is collected and contained in an integrated storage

	segment of the cannula		segment of the cannula
Imaging during the procedure	Angiography for initial placement with onboard optical coherence tomography on the cannula	Same	Same
Electrical Safety	Class I, Type CF, defibrillation proof IEC 60601-1	Same	Same
Electromagnetic Compatibility	IEC 60601-1-2	Same	Same
Laser Classification	Class I	Class IV	Class I
Provided Sterile	Yes	Yes	Yes
Sterilization Method	e-beam irradiation	Ethylene oxide	e-beam irradiation
Sterility Assurance Level	10^{-6}	Same	Same
Single-use Catheter	Yes	Yes	Yes
Packaging	Placed in a tray contained in a Tyvek pouch	Same	Same
Clinical Characteristics			
Anatomical Site of Use in the Body	Peripheral Vessels	Same	Same
Clinical Condition	Occluded vessels and vascular stents in the peripheral vasculature	Occluded vessels and vascular stents in the peripheral vasculature	Occluded vessels in the peripheral vasculature
Population in which Device is Used	Male or Female Adults	Same	Same
Advancement to the Target Tissue	Over an 0.014 inch guide wire through a vascular sheath	Same	Same
Sheath Compatibility for the Catheter	7 Fr	4 to 7 Fr	7 Fr
Medical Procedure Site	Hospital Cardiac Catheter Lab	Same	Same

	Office-based Lab		
Treatment Method	Atherectomy	Same	Same
Biological Characteristics			
Biocompatibility of Materials Used in the Construction of the Cannula	Meets ISO 10993 requirements	Same	Same
Length of Time in Contact with the Target Tissue	< 24 hours	Same	Same

Biocompatibility testing

There have been no new materials or coatings to the Pantheris catheter since review and clearance of K173862, so no new tests were warranted to support this submission. The tests completed and reviewed in K173862 were:

1. Sensitization,
2. Irritation,
3. Systemic toxicity,
4. Materials-mediated pyrogenicity,
5. Hemocompatibility (dog thrombogenicity),
6. Hemocompatibility (platelet and leukocyte – PLC with predicate device),
7. Cytotoxicity,
8. Hemocompatibility (hemolysis direct and indirect),
9. Hemocompatibility (complement activation), and
10. Hemocompatibility (partial thromboplastin time, human plasma).

Electrical safety and electromagnetic compatibility (EMC)

The subject and reference predicate devices comply with IEC 60601-1 standard for electrical safety and the IEC 60601-1-2 standard for electromagnetic compatibility, as reviewed and cleared in K173862.

Software Verification and Validation Testing

The catheter does not contain any software. The software of the Lightbox component of the system was reviewed and cleared in K173862. The software is considered a "moderate" level of concern, per the FDA's Guidance for Industry and FDA Staff, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*.

Performance Testing – Bench

Bench testing was conducted to ensure that the Pantheris catheter performs as intended in an ISR model. Following use of the catheter in this model, the stents were evaluated under 20X magnification and there was no evidence of damage to the stents. In addition, the excised tissue was examined and no stent particulate material—metal—was noted to be present when viewed under 20X magnification. No interaction between the Pantheris catheter and the stents during simulated treatment either a single stent or overlapping stent models, which was confirmed by examination of the stents—there was no evidence of cracks, scratches, permanent set or coating delamination.

Performance Testing – Animal

Preclinical (animal) data were collected from the use of the Pantheris catheter in a simulated ISR model in the pig. Pathologically, acute treatment with the Avinger Pantheris Atherectomy Catheter was associated with no evidence of adverse effects on either the arteries (*e.g.*, no thrombosis or dissection) or the implanted stents (*e.g.*, strut exposure, deformation, or discontinuities/fractures caused by interaction with the cutter), as assessed by light microscopy, radiography, and SEM.

Performance Testing – Clinical

The INSIGHT Trial was a prospective, multi-center, single-arm trial to determine whether the Pantheris System is substantially equivalent in safety and performance outcomes in the treatment of in-stent restenosis in peripheral vessels.

The primary safety endpoint was defined as freedom from a composite of major adverse events (MAEs) through 30 days after the procedure, as adjudicated by an independent Clinical Events Committee (CEC). The primary effectiveness endpoint was technical success, defined as the percent of target lesions that have a residual diameter stenosis ≤ 50% after use of the Pantheris device alone, as assessed by an independent angiographic core laboratory. The secondary safety endpoint was absence of new or worsening stent fracture following use of the Pantheris catheter. A secondary powered effectiveness endpoint was freedom from target lesion revascularization (TLR) at 6 months following the index procedure. Additional secondary effectiveness included procedural success, defined as the percent of target lesions that have residual diameter stenosis ≤ 30% post-Pantheris and any other adjunctive therapy, as determined by an independent core lab, and changes in Ankle- Brachial Index (ABI), and Rutherford Classes at 30 days and 6 months after the procedure in relation to the measurements prior to the procedure.

A total of 97 subjects were enrolled in the INSIGHT trial, with the treated population consisting of subjects presenting with documented symptomatic in-stent restenosis (stenosis ≥70% by visual estimation) and who met all eligibility criteria. The target in-stent restenotic lesion had to be located in vessels with diameters of ≥ 3 mm and ≤ 7 mm and not exceed 30 cm in length. Subjects were followed through 30 days and six months post-procedure. The clinical data for 97 subjects enrolled across 17 investigational sites in the USA (n=15) and EU (n=2) who reported for clinic visits 30 days and 85 subjects who reported for clinic visits 6 months after the index procedure were analyzed.

The primary safety endpoint was defined as freedom from a composite of major adverse events (MAEs) through 30 days after the procedure, as adjudicated by an independent Clinical Events Committee (CEC). Only 3 subjects (3%) experienced a MAE, with 97% of subjects free from MAEs within 30 days. With only 3% subjects reporting an MAE, with a 95% one-sided upper confidence bound of 6.5%, the primary safety performance goal of MAEs occurring in < 20% of subjects was met.

The secondary safety endpoint was absence of new or worsening stent fracture following use of the Pantheris catheter. Only one (1) catheter inadvertently made contact with a stent during the 97 procedures, a rate of 1%. This endpoint was not established with a sample size requirement, so this performance goal was met not only due to its extremely low incidence rate but also by the experience that after re-training of the one physician who had this event on use of real-time optical coherence tomography imaging during the procedure, he completed 12 cases subsequently with no further events.

The primary effectiveness endpoint of this study was technical success, defined as the percent of target lesions that have a residual diameter stenosis ≤ 50% after use of the Pantheris device alone, as assessed by an independent angiographic core laboratory. In this analysis, 86 out of 97 (89%) subjects had ≤50% residual stenosis following use of the Pantheris catheter alone, with a 95% one-sided upper confidence bound of 95% and a lower confidence bound of 82%, which met the adjusted performance goal of > 79%.

A secondary powered effectiveness endpoint was freedom from target lesion revascularization (TLR) at 6 months following the index procedure. The freedom from TLR of the 85 subjects that have completed their 6-month follow-up visits after the index procedure was 93% (79/85), with a 95% one-sided upper confidence bound of 98% and a lower bound of 87%, which met the performance goal of > 61%.

Additional secondary effectiveness included procedural success, defined as the percent of target lesions that have residual diameter stenosis ≤ 30% post-Pantheris and any other adjunctive therapy, as determined by an independent core lab, and changes in Ankle-Brachial Index (ABI), and Rutherford Classes at 30 days and 6 months after the procedure in relation to the measurements prior to the procedure.

Procedural success was determined if the residual diameter stenosis was ≤ 30% following adjunctive treatment. In this cohort 78 of the 97 subjects (80%) were determined to have a residual stenosis ≤ 30% following review of angiograms by the core lab, with a mean stenosis of 15% ±10.1%.

The ABI measures improved 39% from baseline by the time of the 6-month visit and the Rutherford Classification measures improved by 71% at the same time.

Adjunctive devices used in the procedure were primarily balloons (83%), with balloon angioplasty followed by placement of a stent occurring in 13% of the cases, and no adjunctive treatment provided in 4% of the procedures.

In summary:

Substantially equivalent safety and performance outcomes in treating in-stent restenosis with the B-Laser (predicate device) and the Pantheris Catheter (study device).

Conditions and Results	B-Laser System (K181642)	Pantheris System (This Submission)
Sample size	17 enrolled and completing follow-up visit 6 months post-procedure*	97 total enrolled 85 completing follow-up visit 6 months post-procedure
Length of ISR lesion (mean ± SD)	7.6 ± 6.1 cm	13.0 ± 9.6 cm
Percent stenosis of the ISR occlusion prior to treatment (mean ± SD)	85.8 ± 12.8%	83.4 ± 13.8%
Percent stenosis of the ISR occlusion after use of the catheter (mean ± SD)	52.9 ± 11.7%	39.1 ± 12.1%
Percent stenosis of the ISR occlusion after adjunctive therapy (mean ± SD)	17.1 ± 9.9%	15.0 ± 10.1%
Major adverse event (MAE) from procedure to 30 days post-procedure (percent and confidence intervals)	3% 0% to 3.6%	3% 0% to 6.5%
Technical success (percent with residual stenosis < 50% with use of Pantheris catheter alone and confidence intervals)	Not reported	89% 82% to 95%
Freedom from target lesion revascularization at 6 months (percent and confidence intervals)	97% 94% to 100%	93% 87% to 98%
ABI at baseline (mean ± SD)	0.70** (SD not reported)	0.69 ± 0.21

ABI at 6 months post-procedure (mean ± SD)	0.90** (SD not reported)	0.96 ± 0.17
Rutherford Class at baseline (mean ± SD)	2.8 ± 0.6**	2.8 ± 0.84
Rutherford Class at 6 months post-procedure (mean ± SD)	0.7 ± 1.1**	0.8 ± 1.1
Improvement of Rutherford Class at 6 months post-procedure from baseline (percent and confidence intervals)	75%** 59% to 79%	71% 61% to 80%

*Data reported in Rundback J, P Chandra, M Brodmann, B Weinstock, *et al*. Novel laser-based catheter for peripheral atherectomy: 6-month results from the Eximo Medical B-Laser IDE study. *Catheter Cardiovasc Interv* 2019: 1-8 for 17 subjects treated for ISR out of 97 subjects total in this laser atherectomy trial.

**Outcomes for all 97 subjects in this laser atherectomy study; data for the 17 subject ISR cohort were not reported separately from the full study data set for these outcomes.

The results from the INSIGHT trial demonstrate that the Pantheris catheter is safe and effective when used to address in-stent restenosis. The study endpoints achieved the effectiveness performance goals while demonstrating a strong safety profile indicating that the Pantheris catheter can be used to safely excise tissue from occluded vascular stents with precision. The study results also demonstrate extremely low, acute device-related adverse events.

Conclusion

The information submitted in this premarket notification confirms that the addition of in-stent restenosis to the indications for use of the Pantheris System raises no new questions of safety and effectiveness and that the Pantheris catheter is substantially equivalent to the primary predicate device for treatment of in-stent restenosis.