January 6, 2022

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

Re: K212468
Trade/Device Name: Tigereye CTO-Crossing Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU, NQQ
Dated: December 2, 2021
Received: December 3, 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)*
K212468

Device Name
Tigereye CTO-crossing Catheter

Indications for Use *(Describe)*

The Tigereye System is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including sub and chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention using OCT-assisted orientation and imaging. The system is an adjunct to fluoroscopy by providing images of vessel lumen and wall structures. The Tigereye System is contraindicated 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

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	4 January 2022

Proposed Device

Trade Name	Tigereye CTO-Crossing Catheter
Common Name	Tigereye
Regulation Number and Classification Name	21 CFR§870.1250, Catheter for Crossing Total Occlusions 21 CFR§892.1560, Imaging System Optical Coherence Tomography (OCT)
Product Code	PDU, NQQ
Regulatory Class	II

Predicate Device

Trade Name	Tigereye CTO-Crossing Catheter
Common Name	Tigereye
Premarket Notification	K201330
Regulation Number and Classification Name	21 CFR§870.1250, Catheter for Crossing Total Occlusions 21 CFR§892.1560, Imaging System Optical Coherence Tomography (OCT)
Product Code	PDU, NQQ
Regulatory Class	II
Note: This predicate device has not been subject to a design-related recall.	

Device Description and Proposed Modifications

The Tigereye System combines the use of Avinger's optical coherence tomography (OCT) technology with peripheral vascular chronic total occlusion (CTO) crossing capabilities. The Tigereye System consists of the Tigereye CTO-crossing catheter, a Lightbox Sled with integrated umbilical (referred to as "Sled"), and the Lightbox 3 Imaging Console (referred to as "Lightbox 3" or "L300").

The subject device of this submission is a line extension of the Tigereye System reviewed and cleared earlier under K201330.

The Tigereye CTO-crossing catheter is a coaxial 5 French device with a working length of 140 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 Tigereye CTO-crossing crossing head incorporates an optical fiber that allows real-time diagnosis of vessel condition and morphology as well as OCT-guided CTO crossing during the procedure with its connection to an optical Sled and Lightbox 3 imaging console.

The Lightbox 3 console is comprised of a PC and an OCT engine, all contained within a casing. The operator monitor has a touchscreen that allows the user to interact with the console software for controlling the console, monitoring the procedure, and facilitating data input before, during, and after the procedure. The Lightbox 3 console is an optical transceiver, transmitting light to the intraluminal environment through an optical fiber in the catheter and receiving and interpreting the signal from the tissue using a PC-based processing system. The resulting OCT image is displayed on the monitor and provides a qualitative view of the vessel's structure inside traversed vessels as an adjunct to standard imaging techniques (*e.g.*, fluoroscopy) during percutaneous peripheral vascular procedures.

The software of the Lightbox 3 console has been updated to version 1.0.300, which builds on version 4.6.0 that was reviewed and cleared under K201330.

The Tigereye 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) is focused solely on the updates to the software and design of the Lightbox 3 imaging console component of the Tigereye System. The Tigereye CTO-crossing catheter and the Sled in this submission are exactly the same as the catheter and Sled that were cleared in K201330.

Indications for Use

The indication for use for the Tigereye System is:

> The Tigereye System is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including sub and chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention using OCT-assisted orientation and imaging. The system is an adjunct to fluoroscopy by providing images of vessel lumen and wall structures.
>
> The Tigereye system is contraindicated for use in the iliac, coronary, cerebral, renal or carotid vasculature.

Both the subject device and the Tigereye predicate device components of the system have the same intended use of the crossing of chronic total occlusions in order to facilitate placement of guidewires in the peripheral vasculature.

Comparison of Technological Characteristics with the Predicate Device

The Tigereye CTO-crossing catheter is substantially equivalent to the predicate device based upon the following similarities:

Similarities of the Tigereye System (this submission) and the Tigereye System (K201330):

- Both devices are intended to be used to cross chronic total occlusions (CTOs) in peripheral vessels;
- Both devices are used in cardiac catheter labs in either a hospital or an office-based lab;
- Both devices are advanced to the target occlusion through an indwelling vascular sheath;
- Advancement of the both devices is monitored by external fluoroscopy and intravascular OCT imaging;
- Both devices consist of a rotating tip that actively engages the occlusive tissue causing dissection of the tissue on multiple planes, a cannula that creates and sustains a channel through the tissue by compressing the tissue, and a power source to cause the device tip to move the occluding tissue aside;
- Both devices create a channel through the occlusion to facilitate advancement of guidewires and other tools as needed for treatment of the patient; and
- Both devices have equivalent sizes in terms of outer diameter and working length of the cannula.
- Both devices use the OCT imaging software contained in the Lightbox 3 console to measure the lumen of vessels in which they are indwelling;

- Both devices are connected to the Lightbox via an accessory, termed the Sled, that is covered by a sterile drape in order to separate sterile and non-sterile surfaces; and
- Both catheters are packaged in a lidded tray made from identical materials that then is placed within a pouch and then sealed.

Comparison of the Tigereye System (this submission) to the predicate device, the Tigereye System (K201330).

	Subject Device Tigereye System (Avinger, Inc.) (This Submission)	Predicate Device Tigereye System (Avinger, Inc.) K201330
Indication for Use	The Tigereye System is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including sub and chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention using OCT-assisted orientation and imaging. The system is an adjunct to fluoroscopy by providing images of vessel lumen and wall structures. The Tigereye system is contraindicated for use in the iliac, coronary, cerebral, renal or carotid vasculature	Same Same
Intended use	Crossing chronic total occlusions in peripheral arteries using real-time optical coherence tomography assisted	Same

	orientation during catheter intervention	
Product Code	PDU NQQ	Same
Treatment Method	CTO crossing	Same
Technical Characteristics		
Components of the System	Catheter Lightbox 3 Console Sled	Catheter Lightbox 250 Console Sled
Lightbox Imaging Console	Lightbox 3 Software version 1.0.300	Lightbox 250 Software version 4.6.0
Lightbox Imaging Console Use	OCT imaging in peripheral vascular procedures in conjunction with a compatible Avinger product	Same
Compatible Avinger Products	Pantheris atherectomy catheter (K172236) Pantheris SV atherectomy catheter (K182341) Tigereye CTO-crossing catheter (K201330)	Same
Imaging Console dimensions	Height: 27 cm Width: 44 cm Depth: 13 cm	Height: 175 cm Width: 69 cm Depth: 71 cm
Lightbox Imaging Console Weight	≤ 25 pounds	< 260 pounds
Imaging Modality	Optical coherence tomography	Same
Imaging Energy Type	Near-infrared Light	Same
Laser	Swept Source Laser Class 1	Same
Optical Sensitivity (signal : noise ratio)	90 dB minimum	Same
Imaging Capabilities	OCT-assisted orientation and imaging of vessel lumen and wall structures in the peripheral vasculature to	Same

	facilitate crossing of vessel occlusions. Measurement of lumen by OCT	Same
Electrical Safety	Class I, Type CF, defibrillation proof IEC 60601-1	Same
Electromagnetic Compatibility	IEC 60601-1-2	Same
Laser Safety	21 CFR Part 1040 IEC 60825	Same
Power input voltage	100 –240 V 50/60 Hz	Same
Optical output power	14 mW (imaging laser) 35 µW (aiming laser)	Same
Optical source wavelength	1245 – 1375 nm	1260 – 1370 nm
A lines per frame	3000 (min)	1000 (min)
A-scan range in saline	~ 5.3 mm	~ 3 mm
A-scans/second	100,000 Hz	20,000 Hz
Dynamic range	> 100 dB	> 50 dB
Pulse duration	≤ 10 µs	30 µs
Axial resolution	≤ 20 µm	Same
Lateral resolution	< 300 µm (in water)	Same
Imaging range	4 mm	3.3 mm
Imaging speed (frame rate)	8 Hz (min) 33 Hz (max)	Same
Method of inputting information about the case and device selection	Touch screen user interface on the operator monitor for both case information input and procedure options	Typing information on a keyboard to input case information and procedure options with a trackball pointing device located on the top surface of the console cart
Console display resolution (w x h)	3240 x 2160	2560 x 1440
Software Level of Concern	Moderate	Moderate

Operational Characteristics of the Catheter		
Outer diameter of the cannula	1.67 mm (5Fr)	Same
Tip geometry	Spiral flutes	Same
Tip deflection range	Can be modified during the procedure from 0 to 0.28 inch	Same
Working length of the catheter	140 cm	Same
Depth of insertion markings on the shaft	Yes	Yes
Sheath compatibility for the catheter	5 Fr	5 Fr
Rotation speed (max)	1000 RPM	Same
OCT imaging sweep/window	360 degrees	Same
Procedure Site	Hospital Cardiac Catheter Lab Office-based Lab	Same
Anatomical Site of Use	Peripheral Vasculature	Same
Treatment Method	CTO crossing	Same
Catheter Provided Sterile	Yes	Yes
Sterility Assurance Level of the Catheter	10^{-6}	Same
Single-use catheter	Yes	Yes
Packaging	Catheter is placed in a lidded tray contained in a Tyvek pouch Imaging console is shipped in a 5 mm thick wall corrugated plastic container with pre-cut foam to support the console	Exactly the same for the catheter Imaging console is shipped in a wooden container with straps holding it to the floor of the container

Performance Data

The performance tests conducted, including design validation and user testing, establishes that the Tigereye CTO-crossing catheter does not raise new questions of the safety and effectiveness from that of the Tigereye System cleared under K201330.

Biocompatibility testing

The Tigereye catheter is manufactured from materials with a long history in medical devices and passed all tests:

- Cytotoxicity,
- Sensitization,
- Irritation,
- Systemic toxicity,
- Materials-mediated pyrogenicity,
- Hemocompatibility (dog thrombogenicity),
- Hemocompatibility (platelet and leukocyte – PLC with predicate device),
- Hemocompatibility (hemolysis direct and indirect),
- Hemocompatibility (complement activation), and
- Hemocompatibility (partial thromboplastin time, human plasma).

These tests were reviewed in K201330.

The Lightbox 3 console does not contact the patient, so biocompatibility testing was not necessary.

Electrical safety and electromagnetic compatibility (EMC)

The subject and predicate devices comply with IEC 60601-1:2005 AMD1:2012 standard for electrical safety, IEC 60601-1-2:2014 standard for EMC, and IEC 60825-1:2014 standard for laser safety.

Software Verification and Validation Testing

The software of the Lightbox component of the system has been upgraded to version 1.0.300. Software verification and validation testing, as well as regression testing, were conducted and documentation is 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 reviewed in K201330 included:

- Effective length of the device;
- Catheter flush flow rate;
- OCT image generation;
- Catheter field of view;
- Distal tip rotation capability;
- Insertion force of the inner assembly through the hub of the support catheter component;
- Insertion force over a simulated arterial arch;
- OCT image generation and Sled interface capabilities;
- Guidewire compatibility and insertion force through the support catheter component;
- Passive mode life cycle;
- Active mode life cycle;
- Active mode with the tip deflected life cycle;
- Tip deflection cycle;
- OCT image generation and Sled interface;
- Force to cross a simulated occlusion cap;
- Torque shaft torque proof loading;
- Drive shaft torque;
- Proximal section torque shaft torque;
- Flush lumen luer tensile strength;
- Distal catheter joints tensile strength; and
- Proximal catheter joints tensile strength.

The mechanical testing of the Lightbox 3 imaging console included:

- Hipot testing,
- OCT engine laser power,
- OCT image accuracy,
- Console verification testing,
- Console validation testing,
- Electromagnetic compatibility,
- Laser safety,
- Electrical safety,
- Software verification testing, and
- Software validation testing.

Animal Testing

No preclinical testing of the subject device was necessary.

Clinical Studies

No clinical testing of the subject device was necessary.

Conclusion

The information submitted in this premarket notification confirms that the extension of the Tigereye System of CTO-crossing catheters to include the Lightbox 3 imaging console raises no new questions of safety and effectiveness and that the Tigereye catheter with the Lightbox 3 imaging console is substantially equivalent to the predicate device.