April 25, 2023

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

Re: K230594
Trade/Device Name: Tigereye ST CTO-Crossing Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU, NQQ
Dated: March 2, 2023
Received: March 3, 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,

Ariel G. Ash-shakoor -S

Digitally signed by Ariel G. Ash-shakoor -S
Date: 2023.04.25 15:02:22 -04'00'

For

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)*
K230594

Device Name
Tigereye ST CTO-crossing Catheter

Indications for Use *(Describe)*

The Tigereye ST 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.

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	25 April 2023

Proposed Device

Trade Name	Tigereye ST CTO-Crossing Catheter
Common Name	Tigereye ST
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 ST System combines the use of Avinger's optical coherence tomography (OCT) technology with peripheral vascular chronic total occlusion (CTO) crossing capabilities. The Tigereye ST System consists of the Tigereye ST CTO-crossing 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 improvement of the Tigereye CTO-crossing System reviewed and cleared earlier under K201330.

The Tigereye ST 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 ST 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. The software of the Lightbox has been not been updated since the version that was reviewed and cleared under K212468.

The Tigereye ST 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 Tigereye CTO-crossing catheter (K201330) and details additional minor modifications to the design of the Ocelot catheter family to add in functionality of the device.

Indications for Use

The indication for use for the Tigereye ST CTO-crossing catheter is:

> The Tigereye ST 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.

Both the subject device and the predicate device have the exact same intended use of the crossing of chronic total occlusions in order to facilitate placement of guidewires in the peripheral vasculature. The subject device and predicate device have a slight difference in

materials and use the same packaging.

Comparison of Technological Characteristics with the Predicate Devices

Avinger Inc. has identified the Tigereye CTO-crossing catheter (K201330) as the predicate device for the Tigereye ST CTO-crossing catheter.

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

Similarities of Tigereye ST and Tigereye catheters:

- 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.

Comparison of the Tigereye ST CTO-crossing catheter to the predicate device, the Tigereye CTO-crossing catheter.

	Predicate Device Tigereye System 5 French (Avinger, Inc.) K201330	Subject Device Tigereye ST System 5 French (Avinger, Inc.) (This Submission)
Indication for Use	The Tigereye System is intended to facilitate the intraluminal placement of	Same

	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.	
Intended use	Crossing chronic total occlusions in peripheral arteries using real-time optical coherence tomography assisted orientation during catheter intervention	Same
Contraindications	The Tigereye system is contraindicated for use in the iliac, coronary, cerebral, renal or carotid vasculature.	Same
Product Code	PDU NQQ	Same
Treatment Method	CTO crossing	Same
Technical Characteristics		
Components of the System	Catheter Lightbox Imaging Console Sled	Same
Configuration of the catheter	2 components—(1) an outer cannula that acts as a support catheter and (2) an inner assembly that contains a rotating tip and the OCT imaging fiber	2 components—(1) an outer cannula that acts as a support catheter and has a rotating tip, and (2) an inner assembly that contains a rotating tip and the OCT imaging fiber
Imaging Modality	Optical coherence tomography	Same
Imaging Energy Type	Near-infrared Light	Same
Optical Output Power	< 30 mW (Class 1 laser)	Same
Optical Sensitivity	90 db minimum	Same

(signal : noise ratio)		
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	Same 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
Software Level of Concern	Moderate	Same
Sterilization Method	e-beam irradiation	Same
Sterility Assurance Level	10^{-6}	Same
Biocompatibility of Materials	Meets ISO 10993 requirements	Same
Operational Characteristics		
Outer diameter of the cannula	1.67 mm (5 Fr)	Same
Geometry of the tip of the drive shaft	Spiral flutes	Same
Geometry of the tip of the support catheter	N/A this tip is not in the design of Tigereye	3 longitudinal flute elements
Tip deflection range	Can be modified during the procedure from 0 to 0.28 inch	Can be modified during the procedure from 0 to 0.24 inch
Working length of the catheter	140 cm	Same

Sheath compatibility for the catheter	5 Fr	Same
Rotation speeds possible	600, 800, & 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
Provided Sterile	Yes	Yes
Single-use catheter	Yes	Yes

Performance Data

The performance testing conducted establishes that the Tigereye ST CTO-crossing catheter did not raise new questions of the safety and effectiveness from those reviewed and cleared in the Tigereye catheter submission K201330.

Biocompatibility testing

The Tigereye ST catheter was tested and passed the appropriate 10993-1 tests for biocompatibility of materials following eBeam sterilization. The biocompatibility testing performed were:

- Cytotoxicity
- Sensitization – Magnusson-Klingman Method
- Irritation – Intracutaneous Toxicity
- Systemic Toxicity
- Material-mediated Pyrogenicity
- Hemocompatibility – Dog Thrombogenicity
- Hemocompatibility – Hemolysis Direct and Indirect
- Hemocompatibility – Complement Activation.

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.

Software Verification and Validation Testing

The software of the Lightbox component of the system has not been changed since the version that was reviewed and cleared in K212468. The software for this device is considered "moderate" in the level of concern.

Mechanical Testing

The mechanical testing of the subject device 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;
- Drive shaft disengagement;
- Guidewire delivery;
- Tip compression**;**
- Proximal section torque shaft torque;
- Flush lumen luer tensile strength;
- Distal catheter joints tensile strength; and
- Proximal catheter joints tensile strength.

Animal Testing

The performance bench testing was sufficient to demonstrate substantial equivalence to the predicate device.

Clinical Studies

The performance bench testing was sufficient to demonstrate substantial equivalence to the predicate device.

Conclusion

The information submitted in this premarket notification confirms that the extension of the Ocelot Family of CTO-crossing catheters to now include the Tigereye ST catheter raises no new questions of safety and effectiveness and that the Tigereye ST catheter is substantially equivalent to the predicate device.