December 26, 2019

Datascope Corp.
Mark Dinger
Sr. Regulatory Affairs Specialist
15 Law Drive
Fairfield, New Jersey 07004

Re: K190884
Trade/Device Name: TigerPaw Pro Left Atrial Appendage Occlusion Fastener and Delivery Tool
Regulation Number: 21 CFR 878.4750, 21 CFR 870.3470
Regulation Name: Implantable staple, Staple Line Reinforcement Material
Regulatory Class: Class II
Product Code: GDW, FTL
Dated: April 2, 2019
Received: April 4, 2019

Dear Mr. Dinger:

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,

Rachel Neubrander
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190884

Device Name
TigerPaw Pro Flexible LAA Occlusion Fastener and Delivery Tool

Indications for Use *(Describe)*
The TigerPaw Pro is indicated for the occlusion of the left atrial appendage, under direct visualization, in conjunction with other open cardiac surgical procedures.

Direct visualization, in this context, requires that the surgeon is able to see the heart directly, without assistance from a camera, endoscope, etc., or any other viewing technology. This includes procedures performed by sternotomy (full or partial) as well as thoracotomy (single or multiple).

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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TigerPaw Pro Left Atrial Appendage Occlusion Fastener and Delivery Tool

510(k) Summary

Prepared in accordance with 21 CFR Part 807.92

510(k) Number:	K190884
Date Prepared:	23 December 2019
Submitter:	Datascope Corp. 15 Law Drive Fairfield NJ 07004 United States of America
Contact Person:	Mark Dinger
Title:	Sr. Regulatory Affairs Specialist
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Phone:	973-709-7691
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Trade Name:	TigerPaw Pro Left Atrial Appendage Occlusion Fastener and Delivery Tool
Common Name:	Implantable Fastener and Accessories
Classification:	Class II
Classification Name:	Staple, Implantable, GDW Staple Line Reinforcement Material, FTL
Regulation Numbers:	21 CFR 878.4750 21 CFR 870.3470
Predicate Device:	(K111064) TigerPaw System II (SE: 11 May 2011)
Device Description:	The TigerPaw Pro is a flexible, implantable occlusion fastener to be placed on the ostium of the left atrial appendage (LAA) during open cardiac surgical procedures. TigerPaw Pro consists of a Fastener implant that is pre-loaded onto a Delivery Tool and is for single use only. It is designed to provide an alternative to conventional suture and surgical staplers for occlusion of the

ostium of the LAA. The TigerPaw Pro implantable fastener comes in two lengths; 35mm and 45mm. Surgeon judgment based on patient anatomy should determine what length fastener to apply.

Indications for Use: The TigerPaw Pro is indicated for the occlusion of the left atrial appendage, under direct visualization, in conjunction with other open cardiac surgical procedures.

Direct visualization, in this context, requires that the surgeon is able to see the heart directly, without assistance from a camera, endoscope, etc., or any other viewing technology. This includes procedures performed by sternotomy (full or partial) as well as thoracotomy (single or multiple).

Technological Characteristics

The TigerPaw Pro and the predicate device have the following similarities:

- the same intended use,
- the same operating principles,
- incorporates the same basic design and materials,
- sterilized using the same materials and processes has same packaging.

The TigerPaw Pro and the predicate device have the following differences:

- Delivery Tool
    - The Delivery Tool handle was redesigned. The predicate device has two triggers which are actuated in sequence to deploy the fastener. The TigerPaw Pro Delivery tool contains one trigger with a trigger lock button to deploy the fastener.
    - The internal components, jaw, clamp box, roller pins and trigger, were modified to prevent incomplete closure of the TigerPaw Fastener on the LAA.
    - New patient-contacting materials were introduced into the delivery tool.
    - The design of the TigerPaw delivery tool was modified to include a trigger lock mechanism and shaft rotator knob to make the device more user

friendly and to ensure the user performs the deployment steps in the correct sequence.

- Fastener
  - The tips of the fastener needle barbs were blunted to reduce the risk of tissue injury during the procedure

The differences were made to improve device safety and are not considered technological differences that raise new questions of safety and effectiveness.

Safety and Performance:

Datascope Corp., development process completed the following activities to ensure the TigerPaw Pro met its clinically relevant design input requirements and specifications:

- Performance testing, which included the following:
  - Ability to completely close the fastener after deployment and prevent leakage from a mock LAA
  - Tensile strength of the individual fastener barbs after closure
  - Assessment of TigerPaw Pro Delivery Tool jaw component characteristics, including angle measurements
  - Force required to actuate the Delivery Tool trigger, force required to unlock the Delivery Tool lock button, torque required to rotate the Delivery Tool shaft
  - Corrosion testing in accordance with ISO 10555-1 Annex A was performed on the delivery tool and fastener
  - A comparison of TigerPaw II and TigerPaw Pro's Tool jaw to resist flexure while deploying a fastener on a worst-case thickness mock LAA ostium
- A comparison of TigerPaw II and TigerPaw Pro's ability to deploy and secure the fastener connectors under different worst-case rotational forces on a mock ostiumUsability testing on the TigerPaw Pro to obtain clinical user feedback and identify potential usability hazards
- GLP animal study
  - An acute animal study was performed to evaluate the usability of the device and the risk of tissue injury on the LAA during deployment and securement of the fastener. This was demonstrated via an acute Good Laboratory Practices (GLP) animal study on seven canines. Atrial

appendage closure was performed on the right and left atrial appendages on each animal for a total of 14 deployed fasteners. Operative procedures that were evaluated included the ability to access the LAA ostium with the Delivery Tool, assessment of the Delivery Tool and Fastener safety- pre-deployment, ability to reposition the Delivery Tool, deploy the Fastener and remove the Delivery Tool, epicardial assessment of Delivery Tool and Fastener safety and performance-post-deployment and endocardial assessment of Delivery Tool and Fastener safety and performance, post-deployment. A full necropsy examination of the local tissues post device implantation was also performed by a board-certified pathologist. All acceptance criteria were met for this animal study performed using the market version of this device.

- Biocompatibility Testing in accordance with ISO 10993 which included cytotoxicity, sensitization, irritation, acute systemic toxicity, and material mediated pyrogenicity testing

Sterilization – Sterilization validation was completed for the TigerPaw Pro to the requirements of ISO 11135-1:2014. Sterilization is performed with Ethylene Oxide to a Sterility Assurance Level (SAL) of 10^{-6}. Residual limits are in accordance with ISO 10993-7:2008.

The results of the in-vitro tests conducted demonstrate that the functionality and performance characteristics of the device are comparable to the previously cleared TigerPaw System II.

Conclusion:

Based upon the information submitted in this Traditional 510(k) premarket notification, Datascope's TigerPaw Pro is substantially equivalent to the predicate device. The TigerPaw Pro is similar to the predicate device in the intended use and the fundamental scientific technology of the device. The performance and other testing established that the TigerPaw Pro is substantially equivalent to the predicate device.