OCT 2 9 2010

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K101961

Applicant Information:

Date Prepared: July 13, 2010

Name:	LAAx Inc.
Address:	151 Lindbergh Ave, Suite I Livermore CA 94551
Phone:	925-449-4108
Contact Person:	Michael A. Daniel
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Device Information:

Classification:	Class II	
Trade Name:	TigerPaw® System	
Common Name:	Implantable Fastener and Accessories	
Classification Name:	Staple, Implantable, GDW /	Staple Line Reinforcement Material, FTL
Regulation Number:	21 CFR 878.4750	21 CFR 870.3470

Predicate Devices:

The TigerPaw® System is substantially equivalent in intended use and method of operation to a combination of the following predicate devices:

USGI Auto Suture TA & GIA Staplers	K032696
Synovis Surgical Innovations, Peri-Strips Staple Line Reinforcement	K040415

Device Description:

The TigerPaw® System consists of an implantable Fastener and Delivery Tool designed for occlusion of the left atrial appendage, under direct visualization, in conjunction with other open cardiac surgical procedures. The Fastener is composed of linearly spaced connectors over-molded with a soft silicone. The spacing between the connectors along with the silicone gives the Fastener an ability to conform to the anatomy and completely exclude the LAA. The TigerPaw® System also includes a hand-held disposable Delivery Tool. The Delivery Tool

consists of a pistol grip handle with triggers that when actuated close jaws that in turn mate the two sides of the permanently implanted Fastener together.

Intended Use:

The TigerPaw® System 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, or any other viewing technology. This includes procedures performed by sternotomy (full or partial) as well as thoracotomy (single or multiple).

Comparison to Predicate Device(s):

The design of the TigerPaw® System is similar to the USGI device in that they are devices designed to place titanium or stainless steel staples in various types of tissue. The TigerPaw® System is similar to the Synovis predicate in they both use a non-absorbable material to reinforce suture-lines and staple-lines. All devices are packaged sterile and are for single patient use. Further, the TigerPaw® System and the predicate devices have the same or similar intended use.

Device Evaluation:

Extensive bench, animal, and cadaver evaluations were performed on the TigerPaw System. This testing consisted of *in vitro* bench testing, including connector tensile testing and pressure leak testing of fasteners; *in vivo* animal evaluation composed of a total of six acute canine and six chronic canine survived for six months with corresponding histopathology; and *in situ* cadaver evaluation comprising 14 specimens with varying disease history including gross pathology. Finally, a 60 patient clinical study was conducted.

Clinical study: This study was conducted to assess the safety and effectiveness of surgical Left Atrial Appendage (LAA) occlusion, using the LAAx, Inc. TigerPaw® System (delivery system and implant/Fastener), as a concomitant procedure to other open chest cardiac surgery procedures including valve repair / replacement, coronary artery bypass grafting (CABG), and cardiac ablation procedures. The primary safety outcome was the rate of device related adverse (AE) and serious adverse events (SAE) assessed peri-operatively, and at 30 days post procedure. The primary effectiveness outcome was the percentage of patients with complete occlusion of the LAA assessed peri-operatively, both visually (implant/Fastener applied fully across the LAA Os) and via Transesophageal Echocardiography (TEE), and at 90 days post procedure also using TEE. Secondary safety endpoints included Major Adverse Cardiac Event (MACE) rates. Secondary effectiveness endpoints included the assessment of the size of residual LAA cavity remaining after application of the TigerPaw® System compared with a pre-defined target ($\leq$ 6 mm).

There were no unanticipated adverse events (AE) with one minor device-related tissue tear repaired with suture. Complete Left Atrial Appendage (LAA) occlusion was visually confirmed in each of the 60 treated patients and confirmed by Transesophageal Echocardiography (TEE) in 56 patients with one patient requiring adjunctive use of suture to achieve LAA closure. There were zero incidences of bleeding or leakage from the area of the device footprint. Fifty-four out

of 54 evaluable patients followed up at the final 90 day period were confirmed to have complete LAA occlusion via TEE with zero leaks or communication between the LAA and LA and no late device-related AEs.

Summary:

Based upon the intended use, descriptive information, and the *in vitro*, *in vivo*, *in situ*, and clinical performance evaluation provided in this pre-market notification, the TigerPaw® System has been shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

LAAx, INC
c/o Mr. Michael A. Daniel
Regulatory and Clinical Affairs
151 Lindbergh Avenue, Suite I
Livermore CA 94551

OCT 29 2010

Re: K101961
LAAx Inc. TigerPaw® System
Regulation Number: 21 CFR 870.4750
Regulation Name: Staple, Implantable
Regulatory Class: Class II (two)
Product Code: GOW
Dated: September 13, 2010
Received: September 14, 2010

Dear Mr. Daniel:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K101961

OCT 29 2010

510(k) Number (if known): K101961

Device Name: TigerPaw® System

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101961