510(K) SUMMARY

MAY 18 2011

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: TBD

Applicant Information:

Date Prepared: April 15, 2011

Name: LAAx Inc.
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Livermore, CA 94551
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Contact Persons (Primary/Secondary):	Michael A. Daniel	/	Christopher R. Timmons
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Device Information:

Classification: Class II
Trade Name: TigerPaw® System II
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 II is substantially equivalent in intended use and method of operation to the following predicate device:

LAAx, Inc. TigerPaw® System (K101961)

Device Description:

The TigerPaw® System II 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 exclude the LAA. The TigerPaw® System II also includes a hand-held disposable Delivery Tool. The Delivery Tool consists of a pistol grip handle with two triggers that when separately actuated, close opposing jaws thus mating the

two sides of the permanently implanted Fastener, and, then allowing release of the Fastener and opening of the jaws for Delivery Tool removal.

Indications for Use:

The TigerPaw® System II 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 II is essentially the same as the predicate device with design modifications to increase manufacturing efficiencies, make the system less expensive to produce, and add a 1st Trigger Closure visual indicator for redundant confirmation of first trigger closure. This continues to be a device designed to occlude the left atrial appendage under direct visualization. The products share common features such as identical operating principles, same scissor type jaw actuation, same fastener closure distance, and the same 15° angled jaw. The devices are packaged sterile and are for single use.

The TigerPaw® System II and the predicate device have the same intended use: Occlusion of the left atrial appendage, under direct visualization, in conjunction with other open cardiac surgical procedures.

Device Evaluation:

Verification testing provided proof that the modifications met all design specifications. Extensive bench evaluations were performed on the TigerPaw® II System. This testing consisted of *in vitro* bench testing, including connector tensile testing and pressure leak testing of fasteners. Biocompatibility testing provided evidence of continued biocompatibility of the revised device.

Summary:

Based upon the intended use, product technical information, performance testing and biocompatibility information provided in this pre-market notification, the TigerPaw® System II has been shown to be substantially equivalent to the currently cleared predicate device in terms of design, performance and intended use.

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

MAY 18 2011

Re: K111064
TigerPaw® System II
Regulation Number: 21 CFR 870.4750
Regulation Name: Staple, Implantable
Regulatory Class: Class II (two)
Product Code: GDW/FTL
Dated: April 15, 2011
Received: April 18, 2011

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

510(k) Number (if known): K111064

Device Name: TigerPaw® System II

Indications For Use:

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Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 K111064