Cayenne Medical, Inc.
Shima Hashemian
QA/RA Associate Director
16597 N. 92nd Street, Suite 101
Scottsdale, Arizona 85260

March 21, 2018

Re: K180274
Trade/Device Name: Ventix™ Link Knotless Anchor with Inserter
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: January 30, 2018
Received: January 31, 2018

Dear Ms. Hashemian:

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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Device Name: Ventix™ Link Knotless Anchor with Inserter

Indications for Use:

The Cayenne Medical, Inc. Ventix™ Link Knotless Anchors are intended to be used for the reattachment of soft tissue to bone for the following indications:

Shoulder

- Acromioclavicular separation repairs
- Deltoid repairs
- Rotator cuff repairs
- Biceps tenodesis

Knee

- Extra-capsular repairs
  - Medial collateral ligament
  - Lateral collateral ligament
  - Posterior oblique ligament
- Patellar realignment and tendon repairs
- Illiotibial band tenodesis
- Supplementary fixation when used in conjunction with a primary fixation device in ACL repair and reconstruction surgical procedures requiring graft fixation.

Foot and Ankle

- Medial or lateral instability repairs/reconstructions
- Achilles tendon repairs/reconstructions

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

510(k) Summary

Cayenne Medical, Inc.

Ventix™ Link Knotless Anchor with Inserter

Administrative Information

Date of summary: 03/19/2018

Manufacturer Name:
Cayenne Medical, Inc.
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Device Name

Classification Name: Smooth or threaded metallic bone fixation fastener

Trade/Proprietary Name: Ventix™ Link Knotless Anchor with Inserter

Common Name: Suture Anchor

Device Classification

FDA has classified bone screws as Class II devices (21 CFR 888.3040). The product code for Fastener, Fixation, Nondegradable, and Soft Tissue is MBI.

Primary Predicate: Smith & Nephew FOOTPRINT Ultra PK Suture Anchor (K093897)

Device Description

The Ventix™ Link Knotless Anchor is a sterile, manually operated, single procedure anchor device for reattachment of soft tissue to bone. The anchor is preloaded on a disposable inserter. The Ventix™ Link Knotless Anchor incorporates design features that facilitate anchor placement under arthroscopic, open or limited access conditions in soft tissue to bone reattachment procedures. The Ventix™ Link Knotless Anchor is offered in two sizes, 4.75mm and 5.5mm, and can receive up to six suture ends. The anchor is made out of PolyEtherEtherKetone (PEEK). Zimmer Biomet TRU-LINK™, MaxBraid™ and/or MaxBraid™ BroadBand™ Tape, or Force Fiber® USP #1 or #2 sutures are to be only used with the Ventix™ Link Knotless Anchors.

The disposable inserter has a working shaft length (from handle to distal tip of anchor) of 6.1 in (155 mm) with an outer shaft diameter of 0.1875 in (4.76 mm). The inserter shaft is made out of surgical grade stainless steel and the handle is made out of ABS plastic. The inserter facilitates the placement of the implant into a hole prepared in the bone.

Indications for Use

The Cayenne Medical, Inc. Ventix™ Link Knotless Anchor is intended to be used for fixation of soft tissue to bone for the following indications:

Shoulder

- Acromioclavicular separation repairs
- Deltoid repairs
- Rotator cuff repairs
- Biceps tenodesis

Knee

- Extra-capsular repairs
  - Medial collateral ligament
  - Lateral collateral ligament
  - Posterior oblique ligament
- Patellar realignment and tendon repairs
- Illiotibial band tenodesis
- Supplementary fixation when used in conjunction with a primary fixation device in ACL repair and reconstruction surgical procedures requiring graft fixation.

Foot and Ankle

- Medial or lateral instability repairs/reconstructions
- Achilles tendon repairs/reconstructions

Technological Differences

The Ventix™ Link Knotless Anchor is similar in its indication for use, intended use, design features, technology, and materials to the predicate device.

The subject Ventix™ Link device has the same intended use and similar indication for use as the predicate device, the Smith & Nephew FOOTPRINT Ultra PK Suture Anchor.

The subject device differs from the predicate device, Smith & Nephew FOOTPRINT Ultra PK Suture Anchor, in terms of design features and the offered sizes.

Non-clinical Testing

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence is included. The results of mechanical testing (pull-out strength), and assessment of biocompatibility, pyrogenicity, shelf-life and MRI safety demonstrated that the functionality and safety of the Ventix™ Link Knotless Anchor are adequate for its intended use and determination of substantial equivalence to the predicate device.

Clinical Testing

Clinical testing was not used to establish substantial equivalence to predicate device.

Equivalence to Marketed Product

Cayenne Medical, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the Ventix™ Link Knotless Anchor is substantially equivalent in indication and performance to the legally marketed predicate device, Smith & Nephew FOOTPRINT Ultra PK Suture Anchor (K093897). The substantial equivalence of Ventix™ Link Knotless Anchor is based on similarities in indications for use, intended use, design features, technology, and materials to the predicate device.