October 5, 2019

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

Re: K192428
Trade/Device Name: AFX® Femoral Implant 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: September 3, 2019
Received: September 5, 2019

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. 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,

Laurence D. Coyne, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Device Name: AFX® Femoral Implant with Inserter

Indications for Use:

The AFX Femoral Implant with Inserter is intended for use in tenodesis procedures with soft tissue grafts, utilizing either arthroscopic or open techniques during Anterior Cruciate Ligament (ACL), Posterior Cruciate Ligament (PCL), Medial Collateral Ligament (MCL), Lateral Collateral Ligament (LCL), and Medial Patellofemoral Ligament (MPFL) reconstruction.

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.
Special 510(k): Device Modification

AFX® Femoral Implant with Inserter

ADMINISTRATIVE INFORMATION

Date of summary:

Manufacturer Name:

Cayenne Medical, Inc.
16597 N. 92nd St., Suite 101
Scottsdale, AZ 85260
Telephone +1 (480) 502-3661
Fax +1 (480) 502-3670

Official Contact:

Shima Hashemian
16597 N. 92nd St., Suite 101
Scottsdale, AZ 85260
shashemian@cayennemedical.com
Telephone (480) 458-2196
FAX (480) 502-3670

Device Name

Classification Name: Smooth or threaded metallic bone fixation fastener

Trade/Proprietary Name: AFX® Femoral Implant with Inserter

Common Name: Bone screw

Predicate device: AFX® Femoral Implant with Inserter (K161033)

Device Classification

FDA has classified bone fixation fasteners as Class II devices (21 CFR 888.3040). The product code for Fastener, Fixation, Nondegradable, and Soft Tissue is MBI. These devices are reviewed by Orthopedic Joint Devices Branch.

INTENDED USE

The AFX® Femoral Implant with Inserter is intended for use in tenodesis procedures with soft tissue grafts, utilizing either arthroscopic or open techniques during Anterior Cruciate Ligament (ACL), Posterior Cruciate Ligament (PCL), Medial Collateral Ligament (MCL), Lateral Collateral Ligament (LCL), and Medial Patellofemoral Ligament (MPFL) reconstruction.

DEVICE DESCRIPTION AND COMPARISON WITH PREDICATE DEVICE

The AFX Femoral Implant with Inserter is a non-absorbable internal fixation device used in arthroscopic or open cruciate ligament reconstruction to anchor tendon grafts (such as the hamstring tendon) within a surgically created femoral tunnel to enable tissue ingrowth with the resultant formation of a permanent bony attachment.

The predicate device implant, AFX Femoral Implant with Inserter, was changed to combine two components, wedge and deployment screw, while rounding the top of the deployment screw to allow for easier insertion into the bone. The integration of the wedge with the deployment screw reduces the total number of components in the subject implant. The overall length of the subject implant has also been increased from 24mm to 25mm due to rounding the top of the deployment screw.

The predicate device inserter was also modified to add a red indicator section to clearly indicate when the device is in drive mode and a locking mechanism as a safety feature to prevent the device from being deployed while in load mode. The mechanism within the implant that deploys the implant in both subject and predicate devices is identical.

NON-CLINICAL TESTING

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence is included. The results of performance testing and mechanical testing demonstrated that functionality and safety of the subject AFX femoral implant are adequate for its intended use and determination of substantial equivalence to the predicate device. Mechanical testing, cyclic and pull-out, were performed on the subject device and the test results met the predetermined specifications. Testing also showed that the AFX femoral implant ultimate pull-out strength was comparable to that of the predicate device. The results of assessment of biocompatibility, sterilization, pyrogenicity, and shelf-life also demonstrated substantial equivalence to the predicate device.

CLINICAL TESTING

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

EQUIVALENCE TO MARKETED PRODUCT

The modified AFX Femoral Implant with Inserter device has the following similarities to the unmodified predicate device:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same polymeric materials, and
- is packaged using the same materials and processes.

In summary, the AFX Femoral Implant with Inserter described in this submission is, in our opinion, substantially equivalent to the predicate device. The data included in this submission demonstrates substantial equivalence to the predicate device listed above. Any differences in the technological characteristics between the subject and predicate device do not raise new issues of safety or efficacy.