DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 3, 2016

Cayenne Medical, Inc.
Shima Hashemian
QA/RA Director
16597 North 92nd Street
Scottsdale, Arizona 85260

Re: K161033
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: July 6, 2016
Received: July 8, 2016

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 Parts 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Vincent J. Devlin -S

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

Enclosure

K161033

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)

[redacted]

510(k) Summary

Cayenne Medical, Inc.
Special 510(k): Device Modification

AFX™ Femoral Implant with Inserter

ADMINISTRATIVE INFORMATION

Date of summary:	04/01/2016
Manufacturer Name:	Cayenne Medical, Inc. 16597 N. 92nd St., Suite 101 Scottsdale, AZ 85260 Telephone +1 (480) 502-3661 Fax +1 (480) 502-3670
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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:	AperFix® AM Femoral Implant with Inserter (K122463)

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.

[redacted]

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.

Modifications to the predicate device, AperFix AM Femoral Implant with Inserter, that are the subject of this submission are confined solely to a line extension consisting of a metal free version of the original 24mm implant.

The screws of the modified 24mm implant differ from that of the original 24mm implant in that the combination of two PEEK screws, compression and deployment, in the modified 24mm implant play the role of the metal central screw in the original 24mm implant. In both the original 24mm and modified 24mm versions of the implant, lateral deflection of the body occurs as the implant is secured in position, however, in the original 24mm implant this occurrence is caused by advancing the head of the metal central screw and in modified 24mm implant this occurrence is caused by advancing the compression screw. In the subject 24 mm device, the unibody engages the wall of the femoral tunnel upon deploying the deployment screw. In the predicate 24 mm device the wings engage the wall of the femoral tunnel upon deploying the central screw.

NON-CLINICAL TESTING

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included. The results of performance testing, including biocompatibility, 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.

[redacted]

CLINICAL TESTING

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

EQUIVALENCE TO MARKETED PRODUCT

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

- 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 does not raise new issues of safety or efficacy.

[redacted]