510(k) Summary

OCT 11 2012

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

AperFix® AM Femoral Implant with Inserter

ADMINISTRATIVE INFORMATION

510(k) Number:	**K122463**
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:	Kereshmeh Shahriari
510(k) Summary Preparation Date	September 11, 2012
Predicate Device	Cayenne Medical AperFix® Femoral Implant with Inserter, K083612

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	AperFix® AM Femoral Implant
Common Name:	Fastener, Fixation, Nondegradable, Soft tissue
Classification Name:	Smooth or threaded metallic bone fixation fastener 21 CFR 888.3040 Class II
Product Code:	MBI
Classification Panel:	Orthopedic Devices
Reviewing Branch:	Orthopedic Joint Devices Branch

INTENDED USE

The AperFix® AM 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 AperFix AM 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 device that are the subject of this submission are confined solely to limited to a line extension consisting of a 24 mm (shortened) version of the original 29 mm implant to enable greater flexibility in tendon graft placement within the femur when clinical conditions (i.e. anatomy and/or deformity) preclude use of the original 29 mm device.

The body wedge and wings of the modified 24 mm device differ from those of the original 29 mm device in that the wings are one piece (as opposed to using an assembly of a wedge, two arms, and two pins). In both the 24 mm and 29 mm versions of the AperFix device, the advancing head of the central screw causes lateral deflection of the body as the implant is secured in position. In the subject 24 mm device, the wings engage the wall of the femoral tunnel upon tightening the central screw. In the predicate 29 mm device the arms engage the wall of the femoral tunnel upon tightening the central screw and wedge.

NON-CLINICAL TESTING

Non-clinical testing data was submitted, referenced, or relied upon to demonstrate substantial equivalence. Mechanical testing was performed on the AperFix AM Femoral Implant with Inserter. It was shown that pull-out strength is comparable to the predicate device. Dimensional analysis was performed on the AperFix AM Femoral Implant with Inserter. Product dimensional analysis met the components and product specifications.

EQUIVALENCE TO MARKETED PRODUCT

The AperFix® AM 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,
- incorporates equivalent metallic materials, and
- is packaged using the same materials and processes.

In summary, the AperFix® AM Femoral Implant with Inserter described in this submission is, in our opinion, substantially equivalent to the predicate devices. 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.

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

Cayenne Medical, Incorporated
% Ms. Kereshmeh Shahriari
Senior Director of Regulatory Affairs, Quality & Compliance
16597 North 92nd Street, Suite 101
Scottsdale, Arizona 85260

OCT 11 2012

Re: K122463
Trade/Device Name: AperFix® AM 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 10, 2012
Received: September 13, 2012

Dear Ms. Shahriari:

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K122463

Device Name: AperFix® AM Femoral Implant with Inserter

Indications for Use:

The AperFix AM Femoral Implant 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___ 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122463