

510(k) Summary

NOV 17 2006

**Cayenne Medical, Inc.
AperFix Femoral Implant with Inserter**

ADMINISTRATIVE INFORMATION

Manufacturer Name: Cayenne Medical, Inc.
8541 E Anderson Drive, Suite 100
Scottsdale, AZ 85255
Telephone (480) 520-3661
FAX (480) 520-3670

Official Contact: Derek Harper

Representative/Consultant: Floyd G. Larson
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, CA 92130
Telephone (858) 792-1235
FAX (858) 792-1236

DEVICE NAME

Classification Names: Screw, fixation, bone
Trade/Proprietary Name: AperFix™ Femoral Implant with Inserter
Common Name: Bone screw

DEVICE CLASSIFICATION

FDA has classified bone screws as Class II devices (21 CFR 888.3040). The product code for screw, fixation, bone is HWC. These devices are reviewed by the Orthopedic Joint Devices Branch

INTENDED USE

The AperFix™ Femoral Implant with Inserter is intended for use with soft tissue grafts to provide tendon to bone fixation during arthroscopic or open ACL reconstruction procedures.

DEVICE DESCRIPTION

The Cayenne Medical AperFix™ Femoral Implant with Inserter is a non-absorbable internal fixation device intended to provide tendon to bone fixation in hamstring tendon arthroscopic or open anterior cruciate ligament (ACL) reconstruction. It includes a body, wedge and two deployable arms with compression pads. AperFix Femoral Implants are available in diameters of 9, 10 and 11 mm with a standard length of 35 mm. Each device is intended for single use and is pre-loaded on a sterile inserter.

The AperFix Femoral Implant with Inserter will be supplied sterile. Sterilization will be accomplished by means of Co⁶⁰ gamma irradiation at a dose of 25-40 kGy .

Mechanical testing was performed on the AperFix Femoral Implant. It was shown that pull-out strength is significantly higher than that of a predicate interference screw.

EQUIVALENCE TO MARKETED PRODUCT

Cayenne Medical, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the AperFix Femoral Implant with Inserter is substantially equivalent in indications and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

PaxMed International, LLC
% Mr. Floyd G. Larson
11234 El Camino Real, Suite 200
San Diego, California 92130

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Re: K062487

Trade/Device Name: AperFix™ 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: HWC
Dated: August 24, 2006
Received: August 25, 2006

Dear Mr. Larson:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

Page 2 – Mr. Floyd G. Larson

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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 240-276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", written over a horizontal line.

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

Enclosure

Indications for Use

510(k) Number (if known): K062487

Device Name: AperFix™ Femoral Implant with Inserter

Indications for Use:

The AperFix™ Femoral Implant with Inserter is intended for use with soft tissue grafts to provide tendon to bone fixation during arthroscopic or open ACL reconstruction procedures.

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)

[Signature]
(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number 11062487