510(k) Summary

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

NOV 2 7 2007

AperFix™ Femoral Implant with Inserter

ADMINISTRATIVE INFORMATION

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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Representative/Consultant:	David J. Collette, MD or Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone +1 (858) 792-1235 Fax +1 (858) 792-1236

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	AperFix™ Femoral Implant with Inserter
Common Name:	Bone screw
Classification Name:	Screw, fixation, bone 21 CFR 888.3040 Class II
Product Code:	HWC
Classification Panel:	Orthopedic Devices
Reviewing Branch:	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 AperFix Femoral Implant with Inserter is a non-absorbable internal fixation device used in arthroscopic or open anterior cruciate ligament (ACL) 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.

EQUIVALENCE TO MARKETED PRODUCT

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 7 2007

Cayenne Medical, Inc
% PaxMed International, LLC
David J. Collette, MD
11234 El Camino Real, Suite 200
San Diego, California 92130

Re: K073054
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: October 26, 2007
Received: October 30, 2007

Dear Dr. Collette:

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,

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): K073054

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 NA (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)

Mark N Milhouse

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(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K073054