K063-70 Pg 1 of 2

510(k) Summary

DEC 14 2006

Cayenne Medical, Inc.

AperFix™ Tibial 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™ Tibial 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™ Tibial 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 Tibial Implant is a device that provides soft tissue compression within the prepared tibial tunnel to anchor the tendon. It includes a screw and a two-part screw sheath. AperFix Tibial Implants are available in diameters of 9, 10 and 11 mm with a standard length of 30 mm. Each AperFix Tibial Implant is supplied with the implant screw pre-loaded on a disposable inserter. The role of the inserter is to assist in implant placement within the tibial tunnel.

The AperFix Tibial Implant screw and sheath are manufactured from PEEK-OPTIMA® LT (polyetheretherketone), a biocompatible polymer manufactured by Invibio Inc.

EQUIVALENCE TO MARKETED PRODUCT

Cayenne Medical, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the AperFix Tibial 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 14 2006

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

Re: K063070
Trade/Device Name: AperFix™ Tibial 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 5 2006
Received: October 6, 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.

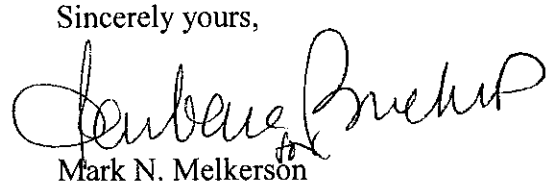
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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.

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,



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): K063070

Device Name: AperFix™ Tibial Implant with Inserter

Indications for Use:

The AperFix™ Tibial 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 No (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 General, Restorative, and Neurological Devices

510(k) Number K063070