JUN - 4 2012

Revised 510(k) Summary

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

CrossFix® II Meniscal Repair Device

ADMINISTRATIVE INFORMATION

510(k) Number: **K121413**

Manufacturer Name:
Cayenne Medical, Inc.
16597 N. 92nd St., Suite 101
Scottsdale, AZ 85260
Telephone (480) 502-3661
FAX (480) 502-3670

Official Contact:
Kereshmeh Shahriari
16597 N. 92nd St., Suite 101
Scottsdale, AZ 85260
kshahriari@cayennemedical.com
Telephone (480) 502-3661
FAX (480) 502-3670

DEVICE NAME

Classification Names: Suture, Nonabsorbable, Synthetic, Polyethylene

Trade/Proprietary Name: CrossFix® II Meniscal Repair Device

Common Name: Suture Punch, Endoscopic Accessories

DEVICE CLASSIFICATION

FDA has classified sutures as Class II devices (21 CFR 878.5000). The product code for Suture, Nonabsorbable, Synthetic, Polyethylene is GAT. These devices are reviewed by the General and Plastic Surgery Branch.

INTENDED USE

The CrossFix® II Meniscal Repair Device is intended for approximation of soft tissue in meniscal repair procedures.

DEVICE DESCRIPTION

The CrossFix® II Meniscal Repair device is a sterile hand-held, manually operated, single procedure suture placement system for meniscus soft tissue approximation procedures.

SUMMARY OF PERFORMANCE TESTS

Product performance test was conducted in a simulated use environment. Device insertion, deployment, and removal were validated.
Bench testing was conducted and showed that the implantable suture meets all predetermined acceptance criteria. These verification tests included suture knot pull out force, suture tensile strength, suture diameter, and handle deployment force.

EQUIVALENCE TO MARKETED PRODUCT

The CrossFix® II Meniscal Repair device 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 CrossFix® II Meniscal Repair device 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 4 2012

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

Re: K121413
Trade/Device Name: CrossFix® II Meniscal Repair Device
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly (ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT
Dated: May 08, 2012
Received: May 11, 2012

Dear Kereshmeh 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): K121413

Device Name: CrossFix® II Meniscal Repair Device

Indications For Use:

The CrossFix® II Meniscal Repair Device is intended for approximation of soft tissue in meniscal repair procedures.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krane for MM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121413