K082518

510(k) Summary

Cayenne Medical, Inc.
Dual Needle Suture Passer System

JAN 16 2009

ADMINISTRATIVE INFORMATION

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	Dual Needle Suture Passer System
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 Dual Needle Suture Passer System is intended for approximation of soft tissue in procedures such as meniscal repair

510(k) Premarket Notification Dual Needle Suture Passer

DEVICE DESCRIPTION

The Dual Needle Suture Passer System is a sterile hand-held, manually operated single procedure suture placement system for soft tissue approximation procedures

Mechanical suture knot pull-out force testing has been conducted on the Dual Needle Suture Passer System It was shown that suture knot pull-out strength is significantly higher than that of a predicate device The proposed device was tested in the animal tissue and meets the knot pull-out strength requirements The proposed device meets USP requirements for non-absorbable sutures

EQUIVALENCE TO MARKETED PRODUCT

Cayenne Medical, Inc demonstrated that for the purposes of FDA's regulation of medical devices, the Dual Needle Suture Passer System 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 Teleflex Medical's Force Fiber™, Non-absorbable Polyethylene Surgical Suture (K063778), CP Medical's CP Fiber Non-absorbable Polyblended Surgical Suture (K041894), DePuy Mitek's (Mitek Worldwide) RAPIDLOC-PDS Mensical Repair System (K023388), Anulex Technologies's Xclose™ Tissue Repair System (K062307), and Smith & Nephew s ULTRA FAST-FIX Meniscal Repair System (K072322)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cayenne Medical, Inc
% Kereshmeh Shahriari
Director of QA & RA
16597 N 92nd Street, Suite 101
Scottsdale, Arizona 85260

JAN 16 2009

Re K082518
Trade/Device Name Dual Needle Suture Passer System
Regulation Number 21 CFR 878 5000
Regulation Name Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class II
Product Code GAT
Dated December 22, 2008
Received December 23, 2008

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

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) 276-0115 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

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

Enclosure

510(k) Premarket Notification Dual Needle Suture Passer

Indications for Use

510(k) Number (if known) K082518

Device Name Dual Needle Suture Passer System

Indications for Use

The Dual Needle Suture Passer System is intended for approximation of soft tissue in procedures such as meniscal repair

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)

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

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