510(k) Summary

OCT 19 2007

Cayenne Medical, Inc.
CapSew™ Plication System

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Cayenne Medical, Inc. 16597 North 92nd Street, Suite 101 Scottsdale, AZ 85260 USA Telephone +1 (480) 502-3661 Fax +1 (480) 502-3670
Official Contact:	Derek Harper
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 email: dcollette@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	CapSew™ Plication System
Common Name:	Suture punch, endoscopic accessories
Classification Regulations:	21 CFR 878.5000, Class II
Product Codes	GAT
Classification Panel:	General and Plastic Surgery
Reviewing Branch:	General and Plastic Surgery

INTENDED USE

The CapSew™ Plication System is intended for use in placement of suture through soft tissue in arthroscopic and open surgical procedures including shoulder capsule tightening.

DEVICE DESCRIPTION

The CapSew™ Plication System is a sterile hand-held, manually operated, single procedure suture placement system for shoulder capsule tightening (plication) procedures. The CapSew Plication System includes one CapSew Plication Device (consisting of a Plication Handle with mounted Suture Cartridge) and one additional CapSew™ Suture Cartridge.

PERFORMANCE TESTING

Mechanical testing has been conducted and data was submitted to demonstrate that the performance of the CapSew™ Plication System is equivalent to that of predicate devices.

EQUIVALENCE TO MARKETED PRODUCT

Cayenne Medical, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the CapSew™ Plication 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: Opus Medical, Inc.'s Opus SpeedStitch™ Suture Device (K042031), CP Medical's CP Fiber, Non-Absorbable Polyblend Surgical Suture (K041894), Teleflex Medical's Force Fiber® Polyethylene Non-Absorbable Surgical Suture (K063778), and Genzyme Surgical Products Polyester Nonabsorbable Surgical Suture (K001434).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 2008

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

Re: K071796
Trade/Device Name: CapSew™ Plication System
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT
Dated: September 26, 2007
Received: October 1, 2007

Dear Dr. Collette:

This letter corrects our substantially equivalent letter of October 19, 2007.

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
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):

Device Name: CapSew™ Plication System

Indications for Use:

The CapSew™ Plication System is intended for use in placement of suture through soft tissue in arthroscopic and open surgical procedures.

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

510(k) Number K071796

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)