510(k) Summary

Cayenne Medical, Inc.

Quattro® GL Suture Anchor

ADMINISTRATIVE INFORMATION

510(k) number:

AUG 16 2013

Date of summary: 04-22-2013

Manufacturer Name:

Cayenne Medical, Inc.
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Official Contact:

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DEVICE NAME

Classification Name: Smooth or threaded metallic bone fixation fastener

Trade/Proprietary Name: Quattro® GL Suture Anchor

Common Name: Suture Anchor

DEVICE CLASSIFICATION

FDA has classified bone screws as Class II devices (21 CFR 888.3040). The product code for this suture anchor is MBI – Fastener, Fixation, Nondegradable, Soft Tissue. These devices are reviewed by the Orthopedic Joint Devices Branch.

INTENDED USE

The Cayenne Medical, Inc. Quattro® GL Suture Anchor is intended for the reattachment of soft tissue to bone for the following indications:

Hip
- Hip capsule repair
  - Acetabular labrum reattachment

Shoulder
- Capsular stabilization
  - Bankart repair
  - Anterior shoulder instability
  - SLAP lesion repairs
  - Capsular shift or capsulolabral reconstructions
- Acromioclavicular separation repairs
- Deltoid repairs
- Rotator cuff repairs
- Biceps tenodesis

Elbow, Wrist, and Hand
- Biceps tendon reattachment
- Ulnar or radial collateral ligament reconstruction
- Lateral epicondylitis repair

Knee
- Extra-capsular repairs
  - Medial collateral ligament
  - Lateral collateral ligament
  - Posterior oblique ligament
- Patellar realignment and tendon repairs
  - Vastus medials obliquous advancement
- Illiotibial band tenodesis

Foot and Ankle
- Hallux valgus repairs
- Medial or Lateral instability repairs/reconstructions
- Achilles tendon repairs/reconstructions
- Midfoot reconstructions
- Metatarsal ligament/tendon repairs/reconstructions
- Bunionectomy

DEVICE DESCRIPTION

This traditional 501(k) premarket notification is to expand the indications for use for Cayenne Medical Quattro GL Suture Anchor. The Quattro GL (LabraLink) Suture Anchor was cleared per premarket notification K112960. Cayenne seeks to expand the existing indications for use for the subject device to include the indications listed above.

The Quattro® GL Suture Anchor is a sterile, manually operated, single procedure suture anchor. The anchor has two suture eyelets allowing for one or two sutures to be loaded through the eyelets. The suture anchor is mounted on an inserter. The Quattro GL Suture Anchor incorporates design features that facilitate suture anchor placement under arthroscopic, open, or limited access conditions in soft tissue to bone reattachment procedures. The Quattro GL Suture Anchor is only offered in one size, 2.9mm with four suture color options. The anchors are offered in two configurations, single loaded or double loaded sutures. Suture(s) used on the anchor are size # 2 non-absorbable surgical sutures. The Quattro GL inserter has a working length of 25.8 cm with an outer shaft diameter of 3.2 mm. Since the market clearance of this device, the length of the Suture Anchor was decreased from 15mm to 11.4mm. The technological characteristics of the Quattro GL Suture Anchor have not changed.

NON-CLINICAL TESTING

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence is included. Mechanical testing (pull-out strength) was performed on the Quattro GL Suture Anchor and the predicate device. Testing showed that the Quattro GL Suture Anchor ultimate pull-out strength was comparable to that of the predicate device.

EQUIVALENCE TO MARKETED PRODUCT

Cayenne Medical, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the Quattro® GL Suture Anchor is substantially equivalent in indication and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices: Smith & Nephew BIORAPTOR 2.3 PK Suture Anchor (K071586), Quattro® GL (LabraLink) Suture Anchor (K112960), Force Fiber Blue Co-Braid Polyethylene non-absorbable surgical suture (K040472), Force Fiber Black Co-Braid Polyethylene non-absorbable surgical suture (K070673), Force Fiber Green Co-Braid Polyethylene non-absorbable surgical suture (K100506), and Force Fiber Blue Polyethylene non-absorbable surgical suture (K092533). The substantial equivalence of Quattro GL Suture Anchor is based on similarities in indications for use, design features, technology, and materials to the predicate device, Bioraptor 2.3 PK Suture Anchor.

The subject device, Quattro GL Suture Anchor with Inserter, has the same intended use, design, technology, materials, manufacturing processes, packaging, sterilization method, and shelf life as the Cayenne Medical Quattro GL (LabraLink) Suture Anchor with Inserter (K112960) and the expansion of indications for use does not introduce new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 16, 2013

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

Re: K131325
Trade/Device Name: Quattro® GL Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 17, 2013
Received: May 20, 2013

Dear Mr. 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 contact 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. 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,

Erin I. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131325

Device Name: Quattro® GL Suture Anchor

Indications for Use:

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Prescription Use (Part 21 CFR 801 Subpart D)	X	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)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices