



Food and Drug Administration
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Silver Spring, MD 20993-0002

Pivot Medical
Ms. Kelly Kucharczyk
Regulatory Affairs Associate Manager
247 Humboldt Court
Sunnyvale, California 94089

July 23, 2015

Re: K151314
Trade/Device Name: CinchLock Flex Knotless 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 14, 2015
Received: May 18, 2015

Dear Ms. Kucharczyk:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K151314

Device Name

CinchLock Flex Knotless Suture Anchor

Indications for Use (Describe)

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 tear repairs Biceps tenodesis

FOOT & ANKLE: Hallux valgus repairs, Medial or lateral instability repairs/reconstructions, Achilles tendon repairs/reconstructions, Midfoot reconstructions, Metatarsal ligament/tendon repairs/reconstructions, Bunionectomy

ELBOW, WRIST, & HAND: Biceps tendon reattachment, Ulnar or radial collateral ligament reconstructions, Lateral epicondylitis repair

KNEE: Extra-capsular repairs (Medial collateral ligament, Lateral collateral ligament, Posterioroblique ligament), Patellar realignment and tendon repairs (Vastus medialis obliquous advancement), Iliotibial band tenodesis

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

I. SUBMITTER

Pivot Medical
247 Humboldt Ct
Sunnyvale, CA 94049

Contact Person: Kelly Kucharczyk, RAC
Associate Manager, Regulatory Affairs
Phone: 810-813-4672
Fax: 303-993-6195

Date Prepared: June 25, 2015

II. DEVICE

Name of Device: CinchLock Flex Knotless Suture Anchor
Common Name: Fastener, Fixation, Nondegradable, Soft Tissue
Classification Name: Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)
Regulatory Class: II
Product Code: MBI

III. PREDICATE DEVICE

CinchLock Knotless Suture Anchor, K131769
This predicate has not been subject to any recalls since it was introduced to market.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Pivot Medical is introducing the CinchLock Flex Knotless Suture Anchor as a line extension to the existing CinchLock Knotless Suture Anchor. The CinchLock Flex Knotless Suture Anchor is a non-degradable PEEK suture anchor that is pre-assembled to a stainless steel inserter. Non-degradable Ultra High Molecular Weight Polyethylene (UHMWPE) suture is provided within the sterile package with the Knotless Suture Anchor and Inserter. The CinchLock Flex Knotless Suture Anchor with Inserter and Suture is provided as a sterile single use device.

V. INDICATIONS FOR USE

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 tear repairs Biceps tenodesis

FOOT & ANKLE: Hallux valgus repairs, Medial or lateral instability repairs/reconstructions, Achilles tendon repairs/reconstructions, Midfoot reconstructions, Metatarsal ligament/tendon repairs/reconstructions, Bunionectomy

ELBOW, WRIST, & HAND: Biceps tendon reattachment, Ulnar or radial collateral ligament reconstructions, Lateral epicondylitis repair

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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The intent of this premarket notification is to provide the CinchLock Anchor on a flexible delivery system, designated the CinchLock Flex Knotless Suture Anchor. In order to achieve this, modifications have been made to the design of the inserter, handle, and anchor coupling as compared to the predicate device. There have been no changes to material of the implantable portion of the device, and all other materials have been established to be equivalent to the predicate with respect to performance and biological safety. These modifications have been assessed via risk analysis and verification and/or validation activities and determined to not raise any new questions of safety or effectiveness of the subject device. Given this, the CinchLock Flex Knotless Suture Anchor is substantially equivalent to the predicate CinchLock Knotless Suture Anchor in regard to intended use, technological characteristics, performance attributes, and operational principles.

VII. PERFORMANCE DATA

Non-clinical verification and validation testing has been performed to verify the efficacy of the CinchLock Flex Knotless Suture Anchor as compared to the predicate. This included Insertion Strength, Anchor Coupling Strength, Ultimate Tensile Strength, Anchor Cinch Force, Inserter Moment Testing, Design Validation, Packaging Validation, Sterilization Validation, Shelf Life/Stability Validation, and Biological Safety Assessment. The results of this testing verified that the subject device is substantially equivalent to the predicate, and raises no new questions of safety or effectiveness. Clinical testing was not required to demonstrate substantial equivalence for this submission.

VIII. CONCLUSIONS

The information presented within this special 510(k) premarket notification demonstrates that the CinchLock Flex Knotless Suture Anchor is substantially equivalent to the identified predicate device.