



April 21, 2016

Biomet Manufacturing Corporation
Adam Cargill
Regulatory Affairs Specialist
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581

Re: K153558

Trade/Device Name: Ventix 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: March 23, 2016
Received: March 24, 2016

Dear Mr. Cargill:

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 Parts 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" (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 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,

Lori A. Wiggins -S

for
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)
K153558

Device Name
Ventix Suture Anchor

Indications for Use (Describe)

The Ventix Suture Anchors are indicated for use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, and knee. Specific indications are:

Shoulder: Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, deltoid repair, pectoralis major repair.

Wrist/Hand: Scapholunate ligament reconstruction, ulnar/radial collateral ligament reconstruction.

Ankle/Foot: Lateral stabilization, medial stabilization, Achilles tendon repair/reconstruction, hallux valgus reconstruction, mid- and forefoot reconstruction.

Elbow: Ulnar or radial collateral ligament reconstruction, biceps tendon reconstruction, Lateral epicondylitis repair

Knee: Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis, and patellar ligament/tendon repair, medial patellofemoral ligament (MPFL) repair or reconstruction, quadriceps tendon repair.

Hip: Proximal hamstring repair

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

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Ventix Suture Anchor 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor: Biomet Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581
Establishment Registration Number: 1825034
Phone: (574) 267-6639
Fax: (574) 267-8137

Contact: Adam Cargill
Regulatory Affairs Specialist
Biomet Sports Medicine

Date: December 11, 2015

Subject Device: Trade

Name: Ventix Suture Anchor

Common Name: Soft Tissue Anchor

Classification Name:

- MBI – Fastener, Fixation, Nondegradable, Soft Tissue (21 CFR 888.3040)

Legally marketed devices to which substantial equivalence is claimed:

- K060693 – Allthread PEEK Suture Anchors
- K150768 – JuggerKnot Soft Anchors

Device Description

The Ventix Suture Anchor is a two-piece design consisting of the vented body and the threaded tip preloaded with suture. The anchor will be offered in three sizes: 3.5mm, 4.75mm, and 5.5mm and is manufactured from polyetheretherketone (PEEK). The Ventix Suture Anchor will be loaded onto a disposable inserter and will be available with #2 MaxBraid or 1.5mm ForceFiber OrthoTape suture.

Intended Use and Indications for Use

The Ventix Suture Anchors are indicated for use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, knee, and hip. Specific indications are:



Shoulder: Bankart repair, SLAP lesion repair, acromio- clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, deltoid repair, pectoralis major repair.

Wrist/Hand: Scapholunate ligament reconstruction, ulnar/radial collateral ligament reconstruction.

Ankle/Foot: Lateral stabilization, medial stabilization, Achilles tendon repair/reconstruction, hallux valgus reconstruction, mid- and forefoot reconstruction.

Elbow: Ulnar or radial collateral ligament reconstruction, biceps tendon reconstruction, Lateral epicondylitis repair

Knee: Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis, and patellar ligament/tendon repair, medial patellofemoral ligament (MPFL) repair or reconstruction, quadriceps tendon repair.

Hip: Proximal hamstring repair

Summary of Technological Characteristics

The technological characteristics (materials, design, sizing, and indications) of the Ventix Suture Anchors are similar to the predicate devices or other previously cleared devices with the main difference being the Ventix Suture Anchors have a vented implant when compared to the ALLThread PEEK Suture Anchors.

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** The proposed Ventix Suture Anchors are intended for use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, knee, and hip which is the same as the predicate devices.
- **Indications for Use:** Indications are identical to the predicate devices.
 - **Materials:** The proposed Ventix Suture Anchor uses the identical implant material as the predicate device.
 - **Design Features:** The proposed Ventix Suture Anchor incorporates similar design features as the predicate device.
- **Sterilization:** The proposed Ventix Suture Anchor is provided sterile via ethylene oxide (EtO), the same sterilization method utilized for the predicate devices.

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests
 - Non-clinical laboratory testing was performed to verify the pull-out strength of the Ventix Suture Anchors by mechanical pullout testing as compared to the ALLThread PEEK Suture Anchors for substantial equivalence and the JuggerKnot Soft Anchors for use in expanded indications. The test results indicate that the Ventix Suture Anchors provide statistically equivalent or greater fixation



strength to the predicate devices and would be functional within the intended use.

- Clinical Tests
 - None provided as a basis for substantial equivalence.

Substantial Equivalence Conclusion

The proposed Ventix Suture Anchor has similar intended use, technological characteristics, and mechanical performance as the predicate devices. The performance testing data identified no new risks and substantial equivalence to the legally marketed predicate devices.