DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 8, 2016

Biomet Manufacturing Corporation
Jared Cooper, Ph.D.
Regulatory Affairs Specialist, Sports Medicine
56 East Bell Drive
Warsaw, Indiana 46581

Re: K152262
Trade/Device Name: Ventix Knotless Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: February 5, 2016
Received: February 8, 2016

Dear Dr. Cooper:

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" (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,

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

Indications for Use

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

510(k) Number *(if known)*
K152262

Device Name
Ventix Knotless Anchor

Indications for Use *(Describe)*
The Ventix Knotless Anchor is indicated for use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, and knee. Specific indications as follows:

Shoulder – Bankart repair, SLAP repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, and deltoid repair.

Wrist/Hand - Scapholunate ligament reconstruction and ulnar/radial collateral ligament reconstruction.

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

Elbow – Ulnar or radial collateral ligament reconstruction, biceps tendon reconstruction, and lateral epicondylitis repair

Knee - Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis, patellar ligament/tendon repair, extra-capsular repair, patellar realignment and repair, and Vastus Medialis Obliquus (VMO) Muscle Advancement.

The Ventix Knotless anchors are also indicated for supplementary fixation when used in conjunction with a primary fixation device in ACL repair and reconstruction surgical procedures requiring graft fixation.

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 Knotless 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: Jared Cooper, Ph.D
Regulatory Affairs Manager
Biomet Sports Medicine

Date: February 5, 2016

Subject Device: Trade Name: Ventix Knotless 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:
- K070389 - Biomet PEEK Knotless Anchors

Device Description
The Ventix anchor is a two-piece design featuring a winged tip that fits into the anchor body. The anchor body is vented. The Ventix anchors will be offered in two sizes: 4.75mm and 5.5mm and is manufactured from polyetheretherketone (PEEK). The Ventix anchor will be loaded onto a disposable inserter.

Intended Use and Indications for Use
The Ventix Knotless Anchors are indicated for use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, and knee. Specific indications as follows:

Shoulder – Bankart repair, SLAP repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, and deltoid repair.

Wrist/Hand - Scapholunate ligament reconstruction and ulnar/radial collateral ligament reconstruction.

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

Elbow – Ulnar or radial collateral ligament reconstruction, biceps tendon reconstruction, and lateral epicondylitis repair

Knee - Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis, patellar ligament/tendon repair, extra-capsular repair, patellar realignment and repair, and Vastus Medialis Obliquus (VMO) Muscle Advancement.

The Ventix Knotless anchors are also indicated for supplementary fixation when used in conjunction with a primary fixation device in ACL repair and reconstruction surgical procedures requiring graft fixation.

Summary of Technological Characteristics

The technological characteristics (materials, design, sizing, and indications) of the Ventix Knotless Anchors are similar or identical to the predicate devices or other previously cleared devices.

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

- **Intended Use:** The proposed Ventix Knotless Anchors are intended for use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, and knee which are identical to the predicate device.
- **Indications for Use:** Indications are identical to the predicate device with exception of the expanded indications which are supported in this submission.
- **Materials:** The proposed Ventix Knotless Anchor uses the identical implant material as the predicate device.
- **Design Features:** The proposed Ventix Knotless Anchor incorporates similar design features as the predicate device, in that it is a cannulated fully threaded two-piece design with similar dimensions. The differences are in the symmetrical winged anchor tip compared to the asymmetrical anchor tip of the predicate. Further, the predicate two-piece anchor was loaded on the inserter where the tip and body were not connected. The two-piece Ventix anchor is loaded on the inserter as a single connected anchor.
- **Sterilization:** The proposed Ventix Knotless Anchor is provided sterile via gamma irradiation, the same sterilization method utilized for the predicate device.

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 Knotless Anchor by mechanical testing as compared to the Rattler PEEK Knotless Anchor. The test results indicate that the Ventix Knotless Anchor provides greater fixation strength to the predicate device and would be functional within the intended use.
- Clinical Tests

- None provided as a basis for substantial equivalence.

Substantial Equivalence Conclusion

The proposed Ventix Knotless 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.