



March 5, 2020

Biomet Inc.  
Haley Pioch  
Sr. Regulatory Affairs Specialist  
56 East Bell Drive, PO Box 587  
Warsaw, Indiana 46581

Re: K193402

Trade/Device Name: ALLthread PEEK Suture Anchor  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener  
Regulatory Class: Class II  
Product Code: MBI, HWC  
Dated: December 5, 2019  
Received: December 6, 2019

Dear Ms. Pioch:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laura C. Rose, Ph.D.  
Acting Assistant Director  
DHT6C: Division of Restorative, Repair,  
and Trauma Devices  
OHT6: Office of Orthopedic Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K193402

Device Name

ALLthread PEEK Suture Anchors

Indications for Use (Describe)

The ALLthread PEEK Suture Anchors are indicated for use in soft tissue reattachment procedures in the shoulder. Specific indications for the shoulder include: Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, deltoid 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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 ALLthread PEEK 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 September 13, 2019.

**Sponsor:** Biomet Inc.  
56 East Bell Drive  
PO Box 587  
Warsaw, IN 46581  
Establishment Registration Number: 1825034

**Primary Contact Person:** Haley Pioch  
Sr. Regulatory Affairs Specialist  
Telephone: (412-376-2510 extension 214)

**Secondary Contact Person:** Jared Cooper  
Regulatory Affairs Manager  
Telephone: (574-372-1941)

**Date:** December 05, 2019

**Subject Device:** **Trade Name:** ALLthread PEEK Suture Anchor  
**Common Name:** Suture Anchor

**Classification Name:**

- MBI - Fastener, Fixation, Nondegradable, Soft Tissue, Smooth or Threaded Metallic Bone Fixation Fastener (21 CFR 888.3040)
- HWC– screw, fixation, bone (21 CFR 888.3040)

**Predicate Device(s):**

Primary Predicate3	510(k) Number
ALLthread PEEK Suture Anchor	K060693
ALLthread PEEK Suture Anchor	K080088

**Purpose and Device Description:**

The ALLthread PEEK Suture Anchors are soft tissue anchors with preloaded nonabsorbable polyethylene surgical sutures used to repair and reattach soft tissue to bone and are supplied in both double and triple loaded suture configurations. The ALLthread PEEK Suture Anchors are designed to reattach soft tissue to bone in procedures in the shoulder.

The purpose of this submission is:

- To submit a 510(k) for cumulative changes:
  - Line extension including device configurations with 2 or 3 suture options, a white/black suture option, a white/green suture option and a tapered needle option.
- To update labeling in order to narrow the Indications for Use statements, describe the third suture options, and bring the Instructions for Use up to current practices;
- To ensure that the all of the instrumentation/accessories for use with this system are appropriately associated with a 510(k).

**Intended Use and Indications for Use:**

The ALLthread PEEK Suture Anchor devices are intended for soft tissue fixation.

The ALLthread PEEK Suture Anchors are indicated for use in soft tissue reattachment procedures in the shoulder. Specific indications for the shoulder include: Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, deltoid repair.

**Summary of Technological Characteristics:**

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

- **Intended Use:** Identical to predicate
- **Indications for Use:** Similar to predicate
- **Materials:** Similar to predicate
- **Design Features:** Similar to predicate
- **Sterilization:** Similar to predicate

**Summary of Performance Data: (Nonclinical and/or Clinical)**

**Non-Clinical Tests:**

- Suture tensile strength testing of the ALLthread PEEK Suture Anchor device was performed to verify the strength of the sutures. The test results indicate that the device modifications do not introduce any new risks to implant performance.
- Cyclic loading testing of the ALLthread PEEK Suture Anchors was performed to verify cyclic performance of the threaded anchor implant. The test results indicate that the device and accessory modifications do not introduce any new risks to implant performance.

- Static load testing of the ALLthread PEEK Suture Anchors was performed to verify the pull out strength of the device. The test results indicate that the device and accessory modifications do not introduce any new risks to device performance.
- Insertion torque testing of the ALLthread PEEK Suture Anchors and taps was performed to verify the measured insertion torque of the anchors and taps. The test results indicate that the device and accessory modifications do not introduce any new risks to device performance.
- Needle attachment strength testing of the ALLthread PEEK Suture Anchor devices was performed to verify the minimum force required to detach the suture from needle. The test results indicate that the device and accessory modifications do not introduce any new risks to device performance.
- Bacterial Endotoxins Test (BET) per ANSI/AAMI ST 72:2011 as a part of cleaning validation was performed, demonstrating that the device meets the limit of  $\leq 20$  Endotoxin units (EU)/Device per USP41-NF36 Chapter <161> Medical Devices – Bacterial Endotoxin and Pyrogen Tests.

**Clinical Tests:**

- None provided

**Substantial Equivalence Conclusion:**

The subject ALLthread PEEK Suture Anchor has the same intended use and similar indications for use as the predicate devices. The subject device has similar technological characteristics to the predicates, and the information provided herein demonstrates that:

- any differences do not raise new questions of safety and effectiveness; and
- the subject device is at least as safe and effective as the legally marketed predicate devices.