February 24, 2020

Biomet Inc.
Saveetha Raghupathi
Regulatory Affairs Specialist
56 East Bell Drive, PO Box 587
Warsaw, Indiana 46581

Re: K193451
Trade/Device Name: Titanium Interference Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, MBI
Dated: December 12, 2019
Received: December 13, 2019

Dear Saveetha Raghupathi:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laura C. Rose, PhD
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193451

Device Name
Titanium Interference Screws

Indications for Use *(Describe)*
Titanium Interference Screws are intended for use in fixation of patellar bone-tendon-bone grafts in ACL reconstruction.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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 Titanium Interference Screws 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.
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Warsaw, IN 46581
Establishment Registration Number: 1825034

Primary Contact Person:
Saveetha Raghupathi
Regulatory Affairs Specialist
Telephone: (877-652-0830 ext. 236)

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

Date: December 12, 2019

Subject Device:

Trade Name: Titanium Interference Screws
Common Name: Bone Screw Fixation Device

Classification Name:

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

Predicate Device(s):

Primary Predicate	510(k) Number
Arthrotek Interference Screw	K934469

Purpose and Device Description:

Titanium Interference Screws are metallic bone screws used to provide fixation of patellar bone-tendon-bone grafts during anterior cruciate ligament (ACL) repair.

The purpose of this submission is:

- To submit a 510(k) for cumulative changes made to the system since original clearance:
  - A line extension including part numbers with minor dimensional changes made to screw design;
  - Manufacturing site location change;
- To update labeling in order to bring the Instructions for Use up to current practices.

Intended Use and Indications for Use:

These devices are intended for soft tissue repair and/or reconstruction.

Titanium Interference Screws are intended for use in fixation of patellar bone-tendon-bone grafts in ACL reconstruction.

Summary of Technological Characteristics:

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

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

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

Non-Clinical Tests:

- Cyclic loading testing of Titanium Interference Screws was performed to verify cyclic performance of the device. The test results indicate the device and the modifications do not introduce any new risks to the device performance.
- Failure torque testing of Titanium Interference Screws was performed to verify the failure torque of the device. The test results indicate the device and the modifications do not introduce any new risks to the device performance.
- Insertion torque testing of Titanium Interference Screws was performed to verify the insertion torque of the device. The test results indicate the device and the modifications do not introduce any new risks to the device performance.
- Pull out strength testing of Titanium Interference Screws was performed to verify the pull out strength of the device. The test results indicate the device and the modifications do not introduce any new risks to

the 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 ≤20 Endotoxin units (EU)/Device per USP41-NF36 Chapter <161> Medical Devices – Bacterial Endotoxin and Pyrogen Tests.

The testing indicates that the device performs within the intended use and did not raise any new safety and efficacy issues.

Clinical Tests:

- None provided

Substantial Equivalence Conclusion:

The subject device, Titanium Interference Screws, has identical intended use and indications for use to the predicate device. The subject device has similar technological characteristics to the predicate, 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 device.