November 10, 2020

Biomet Inc.
Janine Kem
Regulatory Affairs Specialist
56 East Bell Drive
Warsaw, Indiana 46581

Re: K193214/S001
Trade/Device Name: WasherLoc™ and No-Profile Screw and Washer Systems, Biomet Cannulated Screw System, Biomet Headless Compression and Twist-Off Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI, HWC
Dated: October 20, 2020
Received: October 21, 2020

Dear Ms. Kem:

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,

for

Laura C. Rose, Ph.D.
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)*

K193214

Device Name

WasherLoc™ and No-Profile Screw and Washer Systems

Indications for Use *(Describe)*

Soft tissue fixation to bone, specifically during ligament reconstructive procedures.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*
K193214

Device Name
Biomet Cannulated Screw System

Indications for Use *(Describe)*

Small Cannulated Screws (4.0mm and smaller diameter) are intended for use in:
1. Fixation of small bones, including those in the foot, patella, ankle, wrist and elbow.
2. Arthrodesis of the foot, wrist and elbow.
3. Small and long bone osteotomies.
4. Fracture fixation of small bones, small bone fragments and long bones.

Large Cannulated Screws (5mm and larger in diameter) are intended for use in:
1. Fixation of fractures in long bones and long bone fragments.
2. Long bone osteotomies (femur, tibia, foot, ankle, olecranon).
3. Arthrodesis, and fracture fixation of the foot and ankle, such as Jones fractures of the fifth metatarsal, and Calcaneal fractures.

Large Cannulated Screws (6.5mm and larger in diameter) are intended for use in:
1. Slipped capital femoral epiphysis
2. Pediatric femoral neck fractures
3. Tibial plateau fractures
4. SI joint disruptions
5. Intercondylar femur fractures
6. Subtalar arthrodesis
7. Fixation of pelvis and iliosacral joint.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

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

510(k) Number *(if known)*
K193214

Device Name
Biomet Headless Compression and Twist-Off Screws

Indications for Use *(Describe)*

The Biomet Headless Compression Screws and Twist-Off Screws are indicated for fixation of bone fractures, fusion of a joint (arthrodesis) or bone reconstruction (osteotomy) of the mid-foot bones, metatarsal and phalanges of the foot or the phalanges, metacarpals and carpals of the hand. In the foot, these include procedures to correct Hallux Valgus (bunions), Hallux Varus and Hallux Rigidus, Hammer toe, Claw toe and Mallet toe.

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 WasherLoc™ and No-Profile Screw and Washer Systems, Biomet Cannulated Screw System and Biomet Headless Compression and Twist-Off 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 August 12, 2005.

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

Contact Person: Janine Kem
Regulatory Affairs Specialist
Telephone: (574-371-0578)

Date: November 06, 2020

Subject Device:

Trade Name	Common Name	Classification Name
WasherLoc™ and No-Profile Screw and Washer Systems	Soft Tissue Fixation Devices	• MBI – Fastener Fixation, Nondegradable, Soft Tissue (21 CFR 888.3040) • HWC – Screw, Fixation, Bone (21 CFR 888.3040)
Biomet Cannulated Screw System	Screw, Fixation, Bone	• HWC – Screw, Fixation, Bone (21 CFR 888.3040)
Biomet Headless Compression and Twist-Off Screws	Screw, Fixation, Bone	• HWC – Screw, Fixation, Bone (21 CFR 888.3040)

Predicate Device(s):

K981967	WasherLoc™, Biomet Sports Medicine Ligament Washer, Lo-Profile, Heckman, and Channel Ligament Screw Systems
K122437	WasherLoc™ and No-Profile Screw and Washer Systems
K140891	Biomet Cannulated Screw System
K143188	3.0mm Biomet Cannulated Screw System
K190035	Headless Compression and Twist-Off Screws

Purpose and Device

Description:

The purpose of this Traditional 510(k) is to move the subject devices from a cold nitric acid bioburden reduction process into a bioburden reduction process using REVOX technology.

WasherLoc™ and No-Profile Screw and Washer Systems

The WasherLoc™ and No-Profile Screw and Washer Systems are internal soft tissue fixation devices that aid in arthroscopic and orthopedic reconstructive procedures. The system includes instrumentation allowing for proper preparation and placement of the soft tissue fixation device.
The No-Profile Screw and Washer System includes titanium alloy (Ti-6Al-4V) screws and washers in various lengths/sizes. Both 4.5mm and 6.0mm diameter screws in lengths from 24mm to 70mm are available. The No-Profile Washers are available in 14mm, 16mm, and 18mm diameters with and without spikes. The spikes on the washers are not intended for additional fixation as used with the No-Profile screws.
The WasherLoc™ Tibial Fixation System includes titanium alloy (Ti-6Al-4V) screws and washers in various lengths and sizes. Both 4.5mm and 6.0mm diameter screws in lengths from 24mm to 60mm are available. The WasherLoc™ Washers are available in 14mm, 16mm, and 18mm diameters with spikes intended for additional fixation.

Biomet Cannulated Screw System

The Biomet Cannulated Screw System is designed for a variety of internal fixation, aiding in the alignment, stabilization, and healing of fractures or osteotomies to the skeletal system. The Biomet Cannulated Screw System has multiple variants included which fluctuate in screw diameters and lengths, and include the associated essential instruments that aid in fracture fixation.
The Biomet Cannulated Screw System consists of screw variants, which are available in diameters of 3.0mm, 4.0mm, 5.0mm, 6.5mm, and 8.0mm. Each screw diameter is accompanied by instruments that are designed specifically for a given diameter. Washers are also part of the Biomet Cannulated Screw System and are sized 3.0mm, 4.0mm, 5.0mm, 6.5mm, and 8.0mm to specifically match each screw diameter. The washers are provided to add additional support under the head of the screw in situations where the bone quality is poor. Washers are also utilized for more surface area contact with the bone which needed in order to maintain proper fixation of the fracture or osteotomy.

Biomet Headless Compression and Twist-Off Screws

The Biomet Headless Compression and Twist-Off Screws are used for fixation of bone fractures, fusion of a joint, or bone reconstruction, osteotomies of the mid-foot bones, metatarsals

and phalanges of the foot and metacarpals, phalanges and carpals of the hand. The Ti-6Al-4V alloy Biomet Headless Compression and Twist-Off Screws have multiple lengths and diameters associated with the different screws ranging from 2.0 to 3.0mm in diameter and lengths from 8 to 40mm. Both sets of screws will be available in sterile and non-sterile configurations. The screws include the associated essential instruments that aid in fracture fixation.
The Biomet Headless Compression Screw is a cannulated headless screw which is inserted below the bone surface. This feature helps to minimize soft tissue irritation by sitting recessed and provides compression due to a dual thread design in the shaft and head.
The Biomet Twist-Off Screw is a solid one-piece screw that has a drive shaft that has the ability to connect to a drill or large diameter pin driver. In addition, the screw incorporates a breakaway zone between the head and direct connection that allows the screw to break-off cleanly upon insertion. The Biomet Twist-Off Screw also has compression capabilities with a thread-free segment that achieves compression at the osteotomy site.

Intended Use and Indications for Use:

WasherLoc™ and No-Profile Screw and Washer Systems

Soft tissue fixation to bone, specifically during ligament reconstructive procedures.

Biomet Cannulated Screw System

Small Cannulated Screws (4.0mm and smaller diameter) are intended for use in:
1. Fixation of small bones, including those in the foot, patella, ankle, wrist and elbow.
2. Arthrodesis of the foot, wrist and elbow.
3. Small and long bone osteotomies.
4. Fracture fixation of small bones, small bone fragments and long bones.

Large Cannulated Screws (5mm and larger in diameter) are intended for use in:
1. Fixation of fractures in long bones and long bone fragments.
2. Long bone osteotomies (femur, tibia, foot, ankle, olecranon).
3. Arthrodesis, and fracture fixation of the foot and ankle, such as Jones fractures of the fifth metatarsal, and Calcaneal fractures.

Large Cannulated Screws (6.5mm and larger in diameter) are intended for use in:
1. Slipped capital femoral epiphysis
2. Pediatric femoral neck fractures

3. Tibial plateau fractures
4. SI joint disruptions
5. Intercondylar femur fractures
6. Subtalar arthrodesis
7. Fixation of pelvis and illiosacral joint.

Biomet Headless Compression and Twist-Off Screws

The Biomet Headless Compression Screws and Twist-Off Screws are indicated for fixation of bone fractures, fusion of a joint (arthrodesis) or bone reconstruction (osteotomy) of the mid-foot bones, metatarsal and phalanges of the foot or the phalanges, metacarpals and carpals of the hand. In the foot, these include procedures to correct Hallux Valgus (bunions), Hallux Varus and Hallux Rigidus, Hammer toe, Claw toe and Mallet toe.

Summary of Technological Characteristics:

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

- **Intended Use:** The intended use of the subject devices is the same as the predicate devices.
- **Indications for Use:** The indications for use of the subject devices is similar to the predicate devices.
- **Materials:** The materials used in the subject devices are the same as the predicate devices.
- **Design Features:** The design features of the subject devices are similar to the predicate devices.
- **Sterilization:** The sterilization method of the subject devices is the same as the predicate devices.

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - Cytotoxicity and analytical testing to assess the effects of the REVOX process on Titanium devices. Tests include: process residuals evaluation and analytical tests including ICP-MS to identify metallic residues and non-volatile compounds.
  - Bioburden reduction process assessment for impact to shelf life.
  - Sterilization validation to assess sterilization dosage and SAL.
  - Bacterial Endotoxin Test (BET) - Testing has been performed to establish product non-pyrogenicity.

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

Substantial Equivalence Conclusion

The subject devices have been shown to be substantially equivalent to the predicate devices. The proposed subject devices have the same intended use and indications for use as the predicate devices. The proposed devices have similar technological characteristics to the predicates, and the differences do not raise new questions of safety and effectiveness.