February 7, 2019

Biomet Inc.
Andrew Steward
Regulatory Affairs Specialist
56 East Bell Drive
Warsaw, Indiana 46582

Re: K190035
Trade/Device Name: 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: HWC
Dated: January 2, 2019
Received: January 8, 2019

Dear Andrew Steward:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali -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

Indications for Use

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

510(k) Number *(if known)*

K190035

Device Name
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.

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 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:

Andrew J. Steward
Regulatory Affairs Specialist
Telephone: (574-373-3314)

Date:

2 January 2019

Subject Device:

Trade Name: Headless Compression and Twist-Off Screws

Common Name: Screw, Fixation, Bone
Classification Name:

- HWC– Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)

Predicate Device(s):

K142658	Headless Compression and Twist-Off Screws	Biomet Inc.

Purpose and Device Description:

The Biomet Headless Compression and Twist-Off Screws consist of bone screws of various lengths and diameters and dimensionally optimized corresponding instruments which are used to aid in the alignment and stabilization of fractures to the skeletal system. The Biomet Headless Compression Screws are a cannulated headless screw, which is inserted below the bone surface. The Biomet Headless Compression Screw helps minimize soft tissue irritation and provides compression due to a dual thread design. The Biomet Twist-Off Screw is a solid one piece screw that has a direct connection to a drill or large diameter pin driver; this allows the screw to breakoff cleanly upon contact. The Biomet Twist-Off Screw also has compression capabilities with a thread-free segment that achieves automatic compression at the osteotomy site.

The purpose of this submission is to introduce two new drivers to be used with the Biomet Headless Compression Screws with a decreased tip-taper length and increased radius of curvature compared to the drivers cleared in K142658.

Intended Use and Indications for Use:

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 Biomet Headless Compression and Twist-Off Screws is the same as those cleared in K142658.
- **Indications for Use:** The indications for use of the Biomet Headless Compression and Twist-Off Screws are the same as the indications for use cleared in K142658.
- **Materials:** The materials used in the Biomet Headless Compression and Twist-Off Screws are the same as those cleared in K142658.
- **Design Features:** The design features of the Biomet Headless Compression and Twist-Off Screws are the same as those cleared in K142658.
- **Sterilization:** The sterilization method for the Biomet Headless Compression and Twist-Off Screws is the same as that cleared in K142658.

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - Non-clinical performance testing including torque to failure testing of the driver and insertion/removal torque tests were performed on the screw to compare breakage and simulated use. Results did not add any new risks regarding safety and effectiveness.

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

Substantial Equivalence Conclusion

The Biomet Headless Compression and Twist-Off Screws have been shown to be substantially equivalent to the predicate devices. Results of preclinical tests and the similarities with legal marketed predicated devices indicate the device will perform within the intended use and no new issues of safety or effectiveness have been raised.