February 7, 2018

Biomet, Inc.
Annette Minthorn
Regulatory Affairs Sr. Specialist
56 East Bell Drive
Warsaw, Indiana 46582

Re: K173826
Trade/Device Name: THP™ Hip Fracture Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDO, KTT, HWC
Dated: December 15, 2017
Received: December 18, 2017

Dear Ms. Minthorn:

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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Katherine D. Kavlock -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)*

K173826

Device Name
THP™ Hip Fracture Plating System

Indications for Use *(Describe)*
The THP™ Hip Fracture Plating System is indicated for use in the open reduction and internal fixation of a wide variety of fractures of the proximal femur: intracapsular fractures and intertrochanteric fractures.

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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BIOMET

Traditional 510(k)
Premarket Notification

510(k) Summary

Sponsor:	Biomet, Inc. 56 East Bell Drive P.O. Box 587 Warsaw, IN 46581 Establishment Registration Number: 1825034
Contact Person:	Annette Minthorn Sr. Specialist, Trauma Regulatory Affairs Telephone: 574-372-4294 Fax: (574) 372-4605
Date:	15 December 2017
Trade Name:	THP™ Hip Fracture Plating System
Common Name:	Fracture Plates and Cortical Screws
Classification Names and References:	JDO - Device, fixation, proximal femoral, implant (21 CFR § 888.3030) KTT – Single/multiple component metallic bone fixation appliances and accessories (21 CFR § 888.3030) HWC - Smooth or threaded metallic bone fixation fastener (21 CFR § 888.3040)
Classification Panel:	Orthopedics/87
Predicate Device(s):	Biomet Hip Fracture Plating System (Biomet, K140018, cleared 04-April-2014) Captured Hip Screw System (Biomet, K813554, cleared 12-January-1982)
Purpose and Device Description:	THP Hip Fracture Plating System is a set of metal plates and associated screws designed to affix to the lateral aspect of the proximal femur and provide fracture stabilization for femoral neck fractures and intertrochanteric fractures.

The THP 5.0mm Cortical Screws are both locking and non-locking. The locking screws contain external threads that can be used to lock the threaded holes on the plate body, while the non-locking screws do not include the external threads to complete this task.

Intended Use:

The THP Hip Fracture Plating System is indicated for use in the open reduction and internal fixation of a wide variety of fractures of the proximal femur: intracapsular fractures and intertrochanteric fractures.

Comparison to Predicate Device:

The THP Hip Fracture Plating System 5.0mm cortical screws are subject of this submission in part to a corrective action. These screws will replace the 4.5mm cortical screws that were cleared in K140018 with the TSP Fracture Plates. These screws were found to have a head breakage issue and thus were recalled. The 5.0mm cortical screws were designed to address the head breakage issue, tested and proven not only eliminate the head breakage, but were also found to be 106.6% stronger than the equivalent 4.5mm TSP in max failure torque, as well as an increase of 21.1% in max failure torque when compared to the equivalent CHS screws (cleared in K813554).

In addition, the THP Hip Fracture Plating System plates underwent the following modifications: removed the posterior guide wire hole, updated anterior guide wire hole to accept 2.5mm guide wire, added proximal sweep for anatomical fit, and replaced compression hole with locking hole (4 hole only). These modifications are the subject of this submission. The original THP plates were cleared in K140018. These plates were not part of the recall. The modifications made are to enhance the plates and do not represent a new worse case.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

- **Shelf Life -** The minimum sterilization dose was verified using method VDmax 25 per ISO 11137-2:2013, "Sterilization of health care products – Radiation Part 2: Establishing Radiation Dose".

- **Biocompatibility** – The minor changes in geometry do not affect the biological safety of the plates, screws, and instruments in this submission. The original

Biocompatibility testing was conducted per ISO 10993-1 and Good Laboratory Practices (21 CFR 58). All testing passed.

- **Bacterial Endotoxin Test (BET)** - Testing has been performed to establish product non-pyrogenicity.

Performance Evaluation –Testing conducted on the proposed device is summarized below.

- Mechanical Testing - Shaft Screws FX00080-09 This study demonstrated that the mechanical strength of the proposed device is statistically equivalent to that of the predicate devices.
- Hip FX Plate Construct Fatigue Testing FX00080-10 - This study demonstrated that the proposed device can withstand a cyclic moment load equal to or greater than the predicate device.
- Hip Fx vs. CHS Plate Construct Fatigue Test FX00080-05 – This study demonstrated that the proposed device can withstand a fatigue load, of the 2 Screw and 3 Screw constructs in a simulated bone with an intertrochanteric fracture, equal to or greater than the predicate device.

Conclusions: The data presented in this submission show that the changes do not affect the safety and/or effectiveness of the subject devices and that the subject devices will perform in a substantially equivalent manner to the predicate devices.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for these devices to show substantial equivalence.