Biomet Orthopedics
Genoa Atwood
Regulatory Affairs, Sr. Specialist
56 East Bell Drive, PO Box 587
Warsaw, Indiana 46581

December 8, 2020

Re: K200196
Trade/Device Name: Taperloc® Complete Hip Stems
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, KWZ, JDI, MAY, MEH, LPH, KWL, KWY
Dated: November 12, 2020
Received: November 13, 2020

Dear Genoa Atwood:

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,

Vesa Vuniqi
Assistant Director
DHT6A: Division of Joint Arthroplasty 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

K200196

Device Name

Taperloc® Complete Hip Stems

Indications for Use *(Describe)*

1. Non-Inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union. Femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
5. Revision procedures where other treatment or devices have failed.

Porous coated components are intended for uncemented biological fixation.

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 Taperloc® Complete Hip Stems 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 Orthopedic 56 East Bell Drive PO Box 587 Warsaw, IN 46581 Establishment Registration Number: 1825034
Primary Contact Person:	Genoa Atwood Regulatory Affairs Sr. Specialist Telephone: (864) 553-9153
Secondary Contact Person:	Rhonda Myers Regulatory Affairs Sr. Project Manager Telephone: (574) 373-9659
Date:	January 2, 2020
Subject Device:	**Trade Name:** Taperloc® Complete Hip Stems **Common Name:** Uncemented porous modular hip prosthesis
Classification Name:	• LZO – Hip joint metal/ceramic/polymer semi constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353) • KWZ– Hip joint metal/polymer constrained cemented uncemented prosthesis (21 CFR 888.3310) • JDI – Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3350) • MAY– Hip joint metal/ceramic/polymer semi- constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353) • MEH– Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353) • LPH – Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3358) • KWL– Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21 CFR 888.3360) • KWY– Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21 CFR 888.3390)

Predicate Device:

Primary Predicate	510(k) Number
Taperloc® Complete Hip Stems	K101086

Purpose and Device Description:

Taperloc® Complete Hip Stems are used for hip arthroplasty.

Taperloc® Complete Hip Stems are an implant device, a porous coated femoral stem intended for uncemented biological fixation. The Taperloc® Complete is a series of hip stems with a bi-planar wedge design, titanium substrate, and proximally circumferential titanium porous plasma sprayed design.

The purpose of this submission is:

- To submit a 510(k) for cumulative changes made to the system since original clearance;
  - The distal profile of the Taperloc Complete 9mm Reduced Distal Profile hip stems was reduced in diameter,
  - The Porous Plasma Spray Process was changed to an automatic process,
  - The manufacturing process was changed from a double forging process step to a single-forging step.

Intended Use and

The Taperloc® Complete Hip Stems are intended for hip joint arthroplasty.

Indications for Use:

1. Non-Inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union. Femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
5. Revision procedures where other treatment or devices have failed.

Porous coated components are intended for uncemented biological fixation.

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:** Similar to predicate

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

Non-Clinical Tests:

- Porous Plasma Spray Coating testing was performed on samples of robotically applied coating versus predicate manually applied coating. Testing included:
  - Tensile (ASTM 1147)
  - Fatigue (ASTM (F1160)
  - Porosity (ASTM F1854)
  - Pore Size (ASTM F1854)
  - Thickness (ASTM F1854)
  - Tabor Abrasion (ASTM F1978)
  - Shear Fatigue (ASTM F1160)
  - Shear Static ASTM (F1044)
  - Roughness (comparison to predicate)

  All testing passed and met the specifications or comparison testing (as applicable) to the predicate devices.

- One-Step Forging Distal Pot Up/Down Fatigue testing was performed on samples of single forged hip stem material and compared to predicate double forged hip stem material. Testing included:
  - Rotating Beam Fatigue (ASTM STP 731)

  All testing passed and met specifications and comparison to the predicate device.

Clinical Tests:

- None provided

Substantial Equivalence Conclusion:

The proposed Taperloc® Complete Hip Stems 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 information provided herein demonstrates that:

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