May 19, 2026

Biomet, Inc.
Neha Sreenath
Regulatory Affairs Senior Specialist
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581

Re: K251270
Trade/Device Name: Taperloc® Complete Hip Stem
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, KWY, KWZ, MAY, MEH, OQG
Dated: April 21, 2026
Received: April 22, 2026

Dear Neha Sreenath:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

LIMIN SUN -S

Limin Sun, Ph.D.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251270

Please provide the device trade name(s).

Taperloc® Complete Hip Stem

Please provide your Indications for Use below.

Biomet Taperloc Complete stems are porous coated femoral stems intended for uncemented biological fixation. They are offered in various sizes and offsets, as well as standard full-length and shortened Microplasty® stem lengths. BoneMaster™ HA coated stems, the only available HA coating for Taperloc Complete stems, are for sale outside the United States only. The Taperloc Complete hip stems can be used for either total or hemi hip arthroplasty.

INDICATIONS

1. Noninflammatory 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.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Date Prepared: May 19, 2026

Contact Details (21 CFR 807.92(a)(1))

Applicant Name:	Biomet, Inc.
Applicant Address:	56 East Bell Drive P.O. Box 587 Warsaw IN 46581 United States
Applicant Contact Telephone:	(475) 373-5666
Applicant Contact:	Ms. Neha Sreenath
Applicant Contact Email:	Neha.Sreenath@zimmerbiomet.com
Applicant Name:	Biomet, Inc.

Device Name (21 CFR 807.92(a)(2))

Device Trade Name:	Taperloc® Complete Hip Stem
Common Name:	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented
Classification Name:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulation Number:	21 CFR 888.3358
Product Code(s):	LPH, KWY, KWZ, MAY, MEH, OQG
Device Trade Name:	Taperloc® Complete Hip Stem

Legally Marketed Predicate Devices (21 CFR 807.92(a)(3))

The predicate devices for subject device of this submission are listed in the table below.

	Device Name	Manufacturer	510(k) Number
Primary Predicate	Taperloc® Complete Size 4mm and XR123 Stems	Biomet Manufacturing Corp	K120030
Additional Predicates	Taperloc® Complete Hip Stems	Biomet Orthopedic	K200196
	Taperloc® Complete Microplasty Hip Stem	Biomet Manufacturing Corp	K110400
	Taperloc® Complete Size 5mm and 6mm	Biomet Manufacturing Corp	K103755

Device Description Summary (21 CFR 807.92(a)(4))

Taperloc® Complete Hip Stems are implanted porous coated femoral stems intended for uncemented biological fixation to replace the human femur in hip arthroplasty. The Taperloc Complete Hip Stems is a series of hip stems with a bi-planar wedge design, titanium substrate, and proximally circumferential titanium porous plasma sprayed design. This design provides for immediate medial-lateral, anterior-posterior and rotational stability. The Taperloc Complete Hip Stems can be used for either total or hemi hip arthroplasty.

The femoral stems have a titanium alloy substrate (Ti-6Al-4V) and circumferential proximal porous plasma spray (PPS) coating. The stems are offered in various sizes and offsets (standard offset, high offset, XR123º) as well as standard full-length and shortened Microplasty stems.

The Taperloc Complete Hip Stem tapered stem design seeks to create a press-fit mechanical interface between the prosthesis and the natural bone in the proximal femur without rigidly constraining or capturing the device distally. The tapered, wedge-shaped design encourages proximal load sharing and an even proximal-to-distal transfer of stresses from the implant to the femur. The flat, wedge-shape also provides for rotational stability while the porous plasma-spray coating is designed to promote implant stability by allowing biological fixation of bone to the implant.

Intended Use/Indications for Use (21 CFR 807.92(a)(5))

Biomet Taperloc Complete stems are porous coated femoral stems intended for uncemented biological fixation. They are offered in various sizes and offsets, as well as standard full-length and shortened Microplasty® stem lengths. BoneMaster™ HA coated stems, the only available HA coating for Taperloc Complete stems, are for sale outside the United States only. The Taperloc Complete hip stems can be used for either total or hemi hip arthroplasty.

INDICATIONS

1. Noninflammatory 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.

Indications for Use Comparison (21 CFR 807.92(a)(5))

The subject device has the same intended use as the predicate devices and the same indications for use as the predicate devices.

Technological Comparison (21 CFR 807.92(a)(6))

The subject device has similar technological characteristics as the identified predicate devices. The rationale for substantial equivalence is based on consideration of the following characteristics:

- Intended Use: Identical to predicate devices.
- Indications for Use: Identical to predicate devices.
- Materials: Identical to predicate devices.
- Design Features: Identical to predicate devices.
- Sterilization: Identical to predicate devices.
- Porous Plasma Spray Coating: Similar to predicate devices.

Any minor differences are addressed via predicate device and / or performance testing, and do not raise new questions of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions (21 CFR 807.92(b))

Non-Clinical Tests:

- Distal Fatigue Testing of Taperloc Complete 133 FP stem per ISO 7206-4
- Distal Fatigue Testing of Taperloc Complete XR 123˚ stem per ISO 7206-4
- Porous Plasma Spray Coating Product Requirements per ASTM F1854, ASTM F1147
- Porous Plasma Spray Coating Product Design Verification Requirements per ASTM F1044, ASTM F1160, ASTM F1978
- Biocompatibility per ISO 10993-1
- Cleaning Validation per ISO 19227

Clinical Tests:
No clinical testing was required to support substantial equivalence.

Conclusion

Non-clinical testing demonstrated that the Taperloc Complete Hip Stems are substantially equivalent to the predicate devices.