July 22, 2021

Smith & Nephew, Inc.
Brad Sheals
Senior Regulatory Affairs Manager
7135 Goodlett Farms Parkway
Cordova, TN 38016

Re: K203175
Trade/Device Name: POLARSTEM Cemented Femoral Stem
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
Dated: June 17, 2021
Received: June 21, 2021

Dear Brad Sheals:

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,

Limin Sun, PhD.
Acting 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 *(if known)*
K203175

Device Name
POLARSTEM Cemented Femoral Stem

Indications for Use *(Describe)*
The POLARSTEM Cemented Femoral Stem is indicated for advanced degeneration of the hip joint as a result of degenerative, post-traumatic or rheumatoid arthritis; fracture or avascular necrosis of the femoral head; failure of previous hip surgery, such as joint reconstruction, internal fixation, arthrodesis, hemiarthoplasty, surface replacement arthoplasty, or total hip replacement.

The POLARSTEM Cemented Femoral Stem is intended for single use only and is to be implanted with bone cement.

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

Submitted by:	Smith & Nephew, Inc. 7135 Goodlett Farms Parkway Cordova, Tennessee 38016
Date of Submission:	July 21, 2021
Contact Person:	Mr. Brad Sheals, MS Sr. Regulatory Affairs Manager T (901) 399-6897 M (901) 288-7141
Name of Device:	POLARSTEM Cemented Femoral Stem
Common Name:	Femoral Stem Cemented
Device Classification Name and Reference:	21 CFR 888.3353 – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	LZO
Predicate Device:	POLARSTEM Standard and Lateral Femoral Stems – K130728 The predicate devices have not been subject to a design related recall.

Device Description:

The subject of this traditional 510(k) is the POLARSTEM Cemented Femoral Stems. The POLARSTEM Cemented are manufactured from stainless steel according to ISO 5832-9. These subject POLARSTEM hip stems include same design features as the POLARSTEM Standard and Lateral Femoral Stem cleared under K130728.

The POLARSTEM cemented is suitable for partial or total replacement of the hip joint to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in skeletally mature individuals.

The POLARSTEM is available for cemented use in 9 sizes of standard stems (125.5mm to 159.5mm), and 8 sizes of lateral stems (131.5mm to 159.5mm).

Indication for Use

The POLARSTEM Cemented Femoral Stem is indicated for advanced degeneration of the hip joint as a result of degenerative, post-traumatic or rheumatoid arthritis; fracture or avascular necrosis of the femoral head; failure of previous hip surgery, such as joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

The POLARSTEM Cemented Femoral Stem is intended for single use only and is to be implanted with bone cement.

The above indications are substantially equivalent to the indications cleared for the POLARSTEM cleared under K130728.

Technological Characteristics

Device comparisons described in this premarket notification demonstrate that the subject device POLARSTEM cemented hip stems are substantially equivalent to the below listed legally marketed predicate devices with regard to intended use, indications for use, design, material and performance characteristics.

Substantial Equivalence Information

The overall design and indications for use for the POLARSTEM Cemented femoral stems are substantially equivalent to the following commercially available predicate devices.

Table: Predicate Devices

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew Orthopaedics AG	POLARSTEM Standard and Lateral Femoral Stems with Ti/HA	K130728	10/10/2013

Performance Testing

To further support a determination of substantial equivalence, mechanical testing was conducted on the POLARSTEM Cemented femoral stem. A review of the mechanical data and the technical memo, indicates that the subject POLARSTEM SS Cemented femoral stem is substantially equivalent to predicate device listed in the table above.

Non-Clinical Performance

- Finite Element Analysis per ISO 7206-4:2010 and ISO 7206-6:2013.
- Biocompatibility per EN ISO 10993-1, including EN ISO 10993-5, EN ISO 10993-9, EN ISO 10993-12, EN ISO 10993-15, and EN ISO 10993-18.
- Neck Fatigue test per ISO 7206-6:2013.
- Distal Fatigue test per ISO 7206-4:2010.
- Range of Motion Analysis per EN ISO 21535.
- Pre-Fatigue Pull-Off Analysis per ASTM F2009-20.
- Pre-Fatigue Torque-to-Failure Analysis per ISO 7206-13:2016.
- Burst Test Ball Head Analysis per ISO 7206-10:2003.
- Corrosion Analysis per ASTM F1875.
- Bacterial Endotoxin Testing per ANSI/AAMI ST72 and per the FDA Guidance, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile," "Pyrogen and Endotoxins Testing: Questions and Answers."

Clinical Performance

- Clinical Evidence
    - Clinical evidence of the subject POLARSTEM SS Cemented Femoral Stem from their outside United States (OUS) use has been provided to support the safety and effectiveness of the subject device.

Conclusion

As previously noted, this 510(k) Premarket Notification is being submitted to request clearance for the subject POLARSTEM SS Cemented Femoral Stem. Based on the similarities to the predicate device(s) and a review of the documentation provided, we believe the subject device is substantially equivalent to the commercially available predicate device listed above.