July 19, 2021

Smith & Nephew, Inc.
Pamela Hopkins
Regulatory Affairs Specialist II
1450 East Brooks Rd
Memphis, Tennessee 38116

Re: K211548
Trade/Device Name: POLARSTEM Calcar Reamer Guide
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, KWY, LWJ, MEH
Dated: May 17, 2021
Received: May 19, 2021

Dear Pamela Hopkins:

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
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211548

Device Name
POLARSTEM™ Calcar Reamer Guide

Indications for Use *(Describe)*

The POLARSTEM™ femoral stems with Ti/HA are 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: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

The POLARSTEM™ with Ti/HA is intended for single use only and is to be implanted without 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. 1450 East Brooks Road Memphis, Tennessee 38116
Revision Date:	July 16, 2021
Contact Person:	Pamela Hopkins, Regulatory Affairs Specialist II T (901) 399-5471 M (901) 427-7303
Name of Device:	POLARSTEM™ Calcar Reamer Guide, an accessory tool that is part of the POLARSTEM™ Collared (Standard and Lateral) and POLARSTEM™ Valgus Femoral Stem with Ti/HA.
Common Name:	Total Hip Joint, Femoral Component
Device Classification Name and Reference:	21 CFR 888.3353 – Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented or Nonporous Uncemented Prosthesis 21 CFR 888.3390 – Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis 21 CFR 888.3360 – Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	LZO, KWY, LWJ, MEH
Predicate Device:	POLARSTEM™ Calcar Reamer Guide, an accessory tool included in K143739 which cleared the POLARSTEM™ Collared (Standard and Lateral) and POLARSTEM™ Valgus Femoral Stem with Ti/HA system

Device Description

The Subject Device is a reusable tool intended to be used with the hip implant POLARSTEM™ Collared (Standard and Lateral) and POLARSTEM™ Valgus Femoral Stem with Ti/HA. The Subject Device is used to prepare the bony bed of the proximal femur to allow implantation of the implant POLARSTEM™ in the femoral bone. The Subject Device is designed to be clipped onto the trial rasp to guide the calcar reamer/planer when preparing the proximal femur for a collared POLARSTEM™ and to define the physical stop of the calcar reamer or planer.

Indications for Use

The POLARSTEM™ femoral stems with Ti/HA are 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: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

The POLARSTEM™ with Ti/HA is intended for single use only and is to be implanted without bone cement.

Technological Characteristics

Device comparisons described in this premarket notification demonstrate that the Subject Device is substantially equivalent to the Predicate Device with regards to indications for use, material, and performance characteristics.

When compared to the Predicate Device, the Subject Device is nearly identical to the predicate instrument, with the exception of the distance between the hook and the rasp. The Subject Device has an improved hook design to reduce the risk of interference of material (bone debris) by adding additional clearance between the hook and the rasp.

Substantial Equivalence Information

The materials and indications for use for the Subject Device are identical to the Predicate Device. The minor design difference between the Subject Device and the Predicate Device (i.e. the distance between the hook and the rasp) do not raise any new or different questions of safety and effectiveness. Therefore, the Subject Device is substantially equivalent to the Predicate Device.

Performance Testing

To further support a determination of substantial equivalence, functional testing was conducted on the Subject Device to evaluate its performance. The principal test method used was cadaver/Sawbone surgery to evaluate the Subject Device's usability, safety, and effectiveness with regard to the associated implants, reference materials and combinable medical devices. Testing demonstrated that the Subject Device met or exceed the performance testing of the Predicate Device.

Conclusion

The subject Calcar Reamer Guide is identical in function, intended use, and materials to the Predicate Device. The minor design difference between the Subject Device and the Predicate Device do not raise any new or different questions of safety and effectiveness. Therefore, the subject Calcar Reamer Guide is substantially equivalent to the legally marketed Predicate Device.