DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 20, 2015

Smith & Nephew, Incorporated
Mr. Jeff Sprague
Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K143739
Trade/Device Name: POLARSTEM Collared (Standard and Lateral) and Valgus Femoral Stem with Ti/HA
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: March 10, 2015
Received: March 11, 2015

Dear Mr. Sprague:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Smith & Nephew POLARSTEM Collared and Valgus Femoral Stem with Ti/HA

510(k) Number (if known): K143739

Device Name: POLARSTEM Collared (Standard and Lateral) and Valgus Femoral Stem with Ti/HA

Indications for Use:

The POLARSTEM Collared and Valgus Stem with Ti/HA (INTEGRATION-PLUS®) 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: 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.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary
Smith & Nephew POLARSTEM Collared and Valgus Femoral Stem with Ti/HA

Submitted by:	Smith & Nephew, Inc. Advanced Surgical Devices Division 7135 Goodlett Farms Parkway Cordova, Tennessee 38016
Date of Summary:	April 1, 2015
Contact Person	Jeff Sprague, Regulatory Affairs T (901) 399-5215 F (901) 721-2736
Name of Device:	POLARSTEM Collared (Standard and Lateral) and Valgus Femoral Stem with Ti/HA
Common Name:	Total Hip Joint, Femoral Component, Cementless
Device Classification Name and Reference:	21 CFR 888.3353 – Hip joint metal/polymer/metal 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

Device Description
The POLARSTEM Collared (Standard and Lateral) and Valgus femoral stems designed for non-cemented use are made of a titanium alloy (Ti-6Al-4V) with a fully porous titanium plasma/hydroxyapatite coating (Ti/HA). The design incorporates a highly polished neck area, distal grooves to increase rotational stability, and a 12/14 taper. The collared and valgus femoral stems are substantially equivalent to the POLARSTEM standard and lateral femoral stem with Ti/HA cleared via K130728.

Intended Use
The POLARSTEM Collared (Standard and Lateral) and Valgus Stem with Ti/HA (INTEGRATION-PLUS®) 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: 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.

The above indications are substantially equivalent to the indications cleared for the POLARSTEM standard and lateral femoral stem with Ti/HA (K130728). The only difference is the removal of the following bullet points as they are considered subsets of the more general indications seen above. Removal of the following points does not change the indications.

- All forms of osteoarthritis
- Patients with hips at risk of dislocation
- Femoral neck fracture or proximal fracture to hip joint

Technological Characteristics
A review of the mechanical data indicates that the POLARSTEM Collared (Standard and Lateral) and Valgus Femoral Stem with Ti/HA is capable of withstanding expected *in vivo* loading without failure.

Substantial Equivalence Information
The overall design, materials, and indications for use for the POLARSTEM Collared (Standard and Lateral) and Valgus Femoral Stem with Ti/HA are substantially equivalent to the following commercially available predicate devices. The Ti/HA coating on the POLARSTEM Collared and Valgus femoral stem is identical in composition, properties, and manufacturing location (Smith & Nephew AG) to the predicate below.

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

The following tests were used as a basis for the determination of substantial equivalence:

- Hip Stem Fatigue Testing
- Range of Motion Analysis

All tests which are in relation to the surface characterization (physical, chemical or mechanical) are discussed in detail in the Ti/HA Coating Master File **MAF – 1762 Amendment 1 and 2** and are not included in this 510(k).

Conclusion

As previously noted, this 510(k) Premarket Notification is being submitted to request clearance for the POLARSTEM Collared (Standard and Lateral) and Valgus Femoral Stem with Ti/HA coated by Smith & Nephew AG. Based on the similarities to the predicate component and a review of the mechanical testing performed, the devices are substantially equivalent to the commercially available predicate device listed above.