DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 3, 2017

Smith & Nephew, Inc.
Jonathan DiMotta
Regulatory Affairs Specialist I
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K172684
Trade/Device Name: Smith & Nephew Inc. ANTHOLOGY™ AFIT 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
Dated: September 5, 2017
Received: September 6, 2017

Dear Mr. DiMotta:

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 (DICE) 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" (21 CFR 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 (DICE) 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,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172684

Device Name

Smith & Nephew, Inc. ANTHOLOGY™ AFIT Hip Stem

Indications for Use *(Describe)*

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

The ANTHOLOGY AFIT Hip Stem is for single use only. The ANTHOLOGY AFIT Hip Stem is intended for cementless use.

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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We are smith&nephew

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	October 2, 2017
Contact Person and Address:	Jonathan DiMotta Regulatory Affairs Specialist I T 901-399-5471 F 901-566-7535
Name of Device:	Smith & Nephew, Inc. ANTHOLOGY™ AFIT Hip Stem
Common Name:	Hip Stem
Device Classification Name and Reference:	21 CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	LPH

Device Description

Subject of this Special premarket notification is the addition of a new stem design to the Smith & Nephew ANTHOLOGY™ Hip System. The ANTHOLOGY Hip System currently consists of the ANTHOLOGY Hip Stems cleared via premarket notification K052792. The proposed devices are ANTHOLOGY™ AFIT Hip Stems, new hip stems that will be marketed as part of the ANTHOLOGY Hip System.

The ANTHOLOGY AFIT Hip Stem represents minor design modifications when compared to the predicate ANTHOLOGY Hip Stem cleared via K052792. The ANTHOLOGY AFIT Hip Stem is manufactured from Titanium alloy (Ti-6Al-4V) per ASTM F1472. The proximal body is both porous-coated per ASTM F67 and hydroxyapatite-coated, the middle section is grit-blasted, and the distal end is glass-beaded. The ANTHOLOGY AFIT Hip Stem will be available in a size range of 3 to 14, in both a high and standard neck offset with a 12/14 taper.

Intended Use

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

The ANTHOLOGY AFIT Hip Stem is for single use only. The ANTHOLOGY AFIT Hip Stem is intended for cementless use.

Technological Characteristics
A review of the existing ANTHOLOGY Hip Stem testing has demonstrated that there are no new issues related to the safety and effectiveness of the subject devices. Clinical data was not needed to support the safety and effectiveness of the subject devices.

"The Limulus Amebocyte Lysate (LAL) test was used to determine the subject devices meets the specified pyrogen limit specification of less than or equal to 20 EU/device."

Substantial Equivalence Information
The subject devices are identical in function, intended use, indications for use, material composition, and very similar in overall design to the ANTHOLOGY Hip Stem cleared via premarket notification K052792**.**

Table 1: Substantially Equivalent Predicate to the ANTHOLOGY AFIT Hip Stem

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	ANTHOLOGY Hip Stem	K052792	October 7, 2005

Conclusion
This Special 510(k) premarket notification is being submitted to request clearance for the ANTHOLOGY AFIT Hip Stem. Based on the similarities to the predicate device and a review of the existing mechanical testing performed, the subject devices are substantially equivalent to the predicate ANTHOLOGY Hip Stem.