Smith & Nephew, Inc.
Konrad Wolfmeyer
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

October 25, 2019

Re: K190847
Trade/Device Name: REDAPT Blade Augments
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 24, 2019
Received: September 26, 2019

Dear Konrad Wolfmeyer:

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,

FOR Vesa Vuniqi
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)*

Device Name
REDAPT Blade Augments

K190847

Indications for Use *(Describe)*

The REDAPT Augments are indicated for:

• 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.

REDAPT Augments are intended for single use only and are to be implanted with bone cement to the mating acetabular shell and without bone cement to the bone interface.

Augments are intended to be used in primary and revision surgeries where the acetabulum has the deficiencies of the acetabular roof, anterior or posterior pillar, medial wall deficiency, and / or protrusion as a result of the indications listed previously.

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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K190847

510(k) Summary
Smith & Nephew – REDAPT Blade Augment

Submitted by: Smith & Nephew, Inc.
Orthopaedic Division
1450 East Brooks Road
Memphis, Tennessee 38116

Date of Summary: March 29, 2019

Konrad Wolfmeyer
Regulatory Affairs Specialist
Phone: (901) 399-1367

Name of Device: REDAPT Blade Augment

Common Name: Acetabular Bone Augments

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

Predicate Devices:

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	REDAPT Augments	K171073	11/21/2017

Device Description

Smith & Nephew has developed the subject REDAPT Blade Augments as a modification to the previously marketed and cleared REDAPT Augments (S.E. K171073 (S.E. 11/21/2017)). Both the subject REDAPT Blade Augments and the existing REDAPT Augments are porous acetabular augments used to fill bone voids (superior/posterior) where significant bone loss is present and a cup alone cannot fill the void. The subject REDAPT Blade Augments are made of titanium alloy (Ti-6Al-4V) using the same additive manufacturing methods and materials as the predicate REDAPT Augments.

The purpose of this 510(k) submission is to add additional geometry augments to the Smith & Nephew REDAPT family of Total Hip System implants.

Indications for Use

The REDAPT Augments are indicated for:

- 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.

REDAPT Augments are intended for single use only and are to be implanted with bone cement to the mating acetabular shell and without bone cement to the bone interface.

Augments are intended to be used in primary and revision surgeries where the acetabulum has the deficiencies of the acetabular roof, anterior or posterior pillar, medial wall deficiency, and / or protrusion as a result of the indications listed previously.

Technological Characteristics
Smith & Nephew has evaluated the subject REDAPT Blade Augment devices to demonstrate substantial equivalence to the predicate REDAPT Augment Devices and determined that the subject devices do not represent a new worst case.

Mechanical verification testing/analysis conducted for the subject device, consistent with the predicate device testing, includes:

- Fatigue Strength
- Post-Fatigue Lever-out

The subject REDAPT Blade Augment devices met the pre-determined acceptance criteria for each intended output. Therefore, design verification testing determined that the subject REDAPT Blade Augments are substantially equivalent to the identified predicate devices, cleared in premarket notification K171073.

Substantial Equivalence Information
The subject REDAPT Blade Augments have the same indications for use/intended use as the predicate REDAPT Augments cleared in K171073 (S.E. 11/21/2017). The subject and predicate device Hip Assembly consists of Acetabular Shells and accessory screws, pegs, screw hold covers, Acetabular Augments, Liners, Femoral Heads and Femoral Stems.

- The subject REDAPT Hip System (Blade Augments) has similar technological features as the predicate REDAPT Augments.
- The subject REDAPT Hip System (Blade Augments) are manufactured from the same material (Titanium Alloy) as the predicate REDAPT Augments.
- The subject REDAPT Hip System (Blade Augments) has the same sterilization method, utilizes the same porous structure and are manufactured in the same manner as the predicate REDAPT Augments.

The submission is to modify the design of the existing REDAPT Augments to allow for additional geometrical designed augments. Therefore, the technological characteristics of the subject REDAPT Blade Augments Device are the similar to the technological characteristics of the predicate device REDAPT Augments K171073 (S.E. 11/21/2017).

Conclusion

Based on the verification evidence activities provided in this pre-market notification application, the subject REDAPT Blade Augments are substantially equivalent to the legally marketed predicate devices: REDAPT Augments cleared in K171073 (S.E. 11/21/2017).