Smith & Nephew, Inc.
Ms. Kim Phan
Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

November 21, 2017

Re: K171073
Trade/Device Name: Smith & Nephew, Inc. REDAPT◊ 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: October 23, 2017
Received: October 24, 2017

Dear Ms. Phan:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

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)*

K171073

Device Name

Smith & Nephew, Inc. REDAPT™ Augments

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.

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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510(k) Summary
Smith & Nephew, Inc. REDAPT◇ Augments

Submitted by:	Smith & Nephew, Inc. Advanced Surgical Devices Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	November 20th, 2017
Contact Person	Kim Phan, Regulatory Affairs Specialist II T: (901) 800-3175 F: (901) 566-7034
Name of Device:	Smith & Nephew, Inc. REDAPT◇ Augments
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	510(k)	Clearance Date
Smith & Nephew, Inc.	Contour Acetabular Rings (Primary)	K962541	09/17/1996
Smith & Nephew, Inc.	REDAPT Porous Shell	K150790	11/16/2015
Stryker	RESTORATION Acetabular Wedge Augments (Reference)	K102019	03/03/2011
Smith & Nephew, Inc.	R3 Multi-Hole Acetabular Shells (Reference)	K092386	11/03/2009
Smith & Nephew, Inc.	R3 Acetabular Shells and Liners (Reference)	K070756	06/06/2007

Device Description
Subject of this Traditional premarket notification are the REDAPT◇ Augments. The subject devices are acetabular augment hip components to be used to fill bone voids where significant bone loss is present and a cup alone cannot fill the void.

Intended 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

The subject REDAPT◇ Augments have the same indications for use/intended use as the CONTOUR Reconstruction Rings cleared in K962541. Both designs of the subject device, Staple and Slice Augments, are composed of the same Titanium alloy, have the same sterilization method, utilize the same porous structure, and are manufactured in the same manner as the REDAPT Porous Shells cleared in K150790. At a high level, the subject and primary predicate device are based on the following same technological elements:

- Address acetabular deficiencies
- Implanted in the acetabulum
- Utilize screws for additional fixation

The following technological differences exist between the subject and predicate devices:

- Geometry
- Size offering
- Additive manufactured using Ti-6Al-4V

Summary of Pre-Clinical Testing

- An engineering analysis was conducted in addition to mechanical testing to determine the worst case shell size to be used with the worst-case augment.
- Mechanical testing was completed on the worst-case products where the constructs completed impaction, fatigue, and lever out testing as well as a post-fatigue microstructure analysis. Results showed that the subject devices successfully completed impaction and fatigue testing and had similar lever-out values as the predicate (K070756). The microstructure was also maintained post-fatigue. Additionally, the subject device had a higher run-out fatigue load compared to the primary predicate device (K962541).

- To evaluate the screw tab strength, static pull through and cantilever bending testing was completed and was shown to be greater than previously cleared devices.
- Corrosion testing was completed on the worst-case products. Results of the testing showed that the subject device was not statistically significant compared to the predicate. Results of the testing showed that the ions and ion amount generated do not pose a biological risk.
- Packaging verification testing was conducted and the results of this testing demonstrated that the product will not be damaged during shipment and will adequately maintain sterility post shipment.
- Chemical extraction testing was completed to analyze any residuals on the final product from the manufacturing process. It was determined that the residuals did not pose a biological risk.
- Bacterial endotoxin testing was completed on representative samples and met the acceptable endotoxin limits as stated in 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," and ANSI/AAMI ST-72.

A review of testing has demonstrated that there are no new issues related to the safety or effectiveness of the subject devices. Clinical data was not needed to support the safety and effectiveness of the subject devices. Device comparisons described in this premarket notification demonstrated that the proposed devices are substantially equivalent to legally marketed predicates with respect to intended use, indications, and performance characteristics.

Conclusion

This Traditional 510(k) Premarket Notification is being submitted to request clearance for the REDAPT® Augments. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to the predicate devices.