Smith & Nephew, Inc.
Bryan Cowell
Senior Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

September 24, 2018

Re: K181366
Trade/Device Name: REDAPT Porous Acetabular Shells
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, OQG, KWZ, LZO, JDI, KWY
Dated: August 28, 2018
Received: August 29, 2018

Dear Bryan Cowell:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Daniel S. Ramsey -S
2018.09.24 11:56:55 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181366

Device Name
REDAPT Porous Acetabular Shell

Indications for Use *(Describe)*

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

The REDAPT Porous Acetabular Shell for use with the POLACUP Dual Mobility System is intended for single use only and is to be implanted without bone cement. The POLARCUP Dual Mobility System is to be implanted in the REDAPT Porous Acetabular Shell with 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
Smith & Nephew REDAPT Porous Acetabular Shells

I. SUBMITTER:

Smith & Nephew, Inc.
Orthopaedic Division
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Phone: (901) 396-1633
Fax: (901) 566-7159

Contact Person: Michael Scott
Date Prepared: September 7, 2018

II. DEVICE

Name of Device: REDAPT Porous Acetabular Shells
Common Name: Acetabular Component
Regulatory Class: 2

Classification Name, Regulation Number, Product Codes,

Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (CFR 888.3358) LPH
Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (CFR 888.3358)OQG
Hip joint metal/polymer constrained cemented or uncemented prosthesis (CFR 888.3310) KWZ
Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (CFR 888.3353) LZO
Hip joint metal/polymer semi-constrained cemented prosthesis (CFR 888.3350)JDI
Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (888-3390) KWY

PREDICATE DEVICE

Primary Predicate REDAPT Porous Acetabular Shells: K150790 (S.E. 11/16/2015)
Predicate 2: POLARCUP Dual Mobility System: K110135 (S.E. 10/14/2011)
Predicate 3: G7 Dual Mobility System: K150522 (S.E. 05/01/2015)
Predicate 4: Trabecular Metal Acetabular Revision System Cemented Constrained Liner K072121 (S.E. 01/07/2008)

The predicate devices have not been subject to a design related recall.

III. DEVICE DESCRIPTION

The REDAPT Porous Acetabular Shell is designed for cementless use on the bone-interfacing surface and is made from titanium alloy (Ti-6Al-4V) powder through an additive manufacturing process. The device design allows for the cementing of liners into the shell and incorporates screw holes for fixation.

The POLARCUP Dual Mobility System consists of a metal shell and plastic liner (or insert). POLARCUP Shell is made from Stainless Steel. The inside of the metal shell is polished, and the outside of the plastic liner is able to articulate against this polished surface. The POLARCUP™ Dual Mobility System is an acetabular hip cup prosthesis.

The subject device consists of a REDAPT Porous Acetabular Shell for use with the POLACUP Dual Mobility System. The REDAPT Porous Acetabular Shell is intended to be implanted without bone cement. The POLARCUP Dual Mobility System is to be implanted in the REDAPT Porous Acetabular Shell with bone cement.

The purpose of this 510(k) submission is to modify the indications for the REDAPT Porous Acetabular Shell to allow for a dual mobility use when used with the POLARCUP Dual Mobility System.

IV. INDICATIONS FOR USE

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

The REDAPT Porous Acetabular Shell for use with the POLARCUP Dual Mobility System is intended for single use only and is to be implanted without bone cement. The POLARCUP Dual Mobility System is to be implanted in the REDAPT Porous Acetabular Shell with bone cement.

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

There are no technological differences between the subject and predicate REDAPT Porous Acetabular Shells K150790 (S.E. 11/16/2015).

There are no technological differences between the POLARCUP Dual Mobility System components and the previously cleared POLARCUP Dual Mobility System components K110135 (S.E. 10/14/2011).

To allow for a dual mobility option for the existing REDAPT Porous Acetabular Shells, this submission allows for the existing POLARCUP Dual Mobility System to be implanted in the REDAPT Porous Acetabular Shells with bone cement.

As the devices are identical to the existing 510(k) cleared devices, the technological characteristics assessed consisted of the compatibility of the two systems.

Bacterial endotoxin testing was completed 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 ST72.

Therefore, the technological characteristics of the subject device are the similar to the technological characteristics of the predicate devices REDAPT Porous Acetabular Shells (S.E. (K150790 (S.E. 11/16/2015) and POLARCUP Dual Mobility System (S.E. K150522 (S.E. 05/01/2015)).

VI. PERFORMANCE DATA

The following performance data are provided in support of the substantial equivalence determination.

Biocompatibility

As part of the compatibility assessment, a biocompatibility evaluation was completed for the combination usage of non-cemented REDAPT Porous Acetabular Shell with the cemented POLARCUP Dual Mobility System.

The biocompatibility evaluation for the combination usage of non-cemented REDAPT Porous Acetabular Shell with the cemented POLARCUP Dual Mobility System was conducted in accordance with FDA's Draft Guidance for Industry and FDA Staff "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process".

The subject REDAPT Porous Acetabular Shell with the POLARCUP Dual Mobility System are permanent implants and will be classified as permanent, >30 day body contact according to ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process".

The subject REDAPT Porous Acetabular Shells are made of titanium-6 aluminum-4 vanadium (Ti-6Al-4V) alloy. The material is considered surgical grade and meets ASTM F1472 standard specification. The Ti-6Al-4V alloy meets the quality and chemical composition given in Smith & Nephew Specifications.

The cemented POLARCUP Shell is made from Stainless Steel INOX M30NW meeting the requirement of ISO 5832-9. The POLARCUP XLPE Insert is made from ultra-high molecular weight polyethylene (UHMWPE) and highly cross-linked UHMWPE (XLPE). The material is considered surgical grade meeting the requirements of ISO 5834-1/2. The quality and processing of the material is controlled by Smith and Nephew specifications.

Biocompatibility evaluation has been completed and a summary rationale has been provided for the subject LEGION Finned Tibial Wedges.

Mechanical testing

To further support a determination of substantial equivalence, non-clinical bench (mechanical) testing was conducted on the proposed REDAPT Porous Acetabular Shell with the cemented POLARCUP Dual Mobility System. Test results demonstrated that the proposed devices are substantially equivalent to the predicate REDAPT Porous Acetabular Shell System.

Mechanical tests/assessments completed were:

- Environmental Corrosion Fatigue
- Fatigue
- Post Fatigue Push-Out
- Lever Out
- Torque to Failure
- Range of Motion
- Tolerance Stack Analysis

The subject devices with pre-determined acceptance criteria met the acceptance criteria for all outputs.

VII. CONCLUSIONS

Based on the verification evidence activities provided in the pre-market notification, the subject REDAPT Porous Acetabular Shell for use with the POLACUP Dual Mobility System is substantially equivalent to the legally marketed predicate devices: REDAPT Porous Acetabular Shells: K150790 (S.E. 11/16/2015), POLARCUP Dual Mobility System: K110135 (S.E. 10/14/2011), G7 Dual Mobility System: K150522 (S.E. 05/01/2015) and Trabecular Metal Acetabular Revision System Cemented Constrained Liner K072121 (S.E. 01/07/2008).