Smith & Nephew, Inc.
John Reabe
Director, Regulatory Affairs
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

October 6, 2020

Re: K201701
Trade/Device Name: R3 HA Coated 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: MBL, LZO, LPH, JDI, MEH, LWJ
Dated: September 3, 2020
Received: September 4, 2020

Dear John Reabe:

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,

Vesa Vuniqi
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)*
K201701

Device Name
R3 HA Coated Acetabular Shells

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K201701 510(k) Summary
R3 HA Coated Acetabular Shells

I. Submitter

Smith & Nephew, Inc.
7135 Goodlett Farms Parkway
Cordova, TN 38016

Contact Person:
John Reabe
Director
Email: john.reabe@smith-nephew.com
Phone: 901-399-6670

Date of Summary: October 1, 2020

II: Device

Proprietary Name:	R3 HA Coated Acetabular Shells
Common Name:	Artificial Hip Prosthesis
Regulatory Class:	Class II
Regulation:	21 CFR Section 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Device Product Codes:	MBL, LZO, LPH, JDI, MEH, LWJ
Panel:	Orthopedic

III. Predicate Devices

Device	Manufacturer	510(k) No.	Clearance Date
Primary Predicate			
Reflection 3 Acetabular System	Smith & Nephew	K060630 K061253 K070756 K092386	06/14/2006 05/31/2006 06/06/2007 11/03/2009
Predicates			
Hip Systems with HA including Reflection Shells with HA	Smith & Nephew	K090982	04/21/2010

IV. Device Description

The R3 HA Coated Acetabular Shells are line additions to the existing R3 Acetabular System. The R3 HA Coated Acetabular Shells have the same design as the existing R3 Shells. The difference is the addition of HA coating. The R3 HA Coated Acetabular

K201701 510(k) Summary
R3 HA Coated Acetabular Shells

Shells will be offered in No-Hole, 3-Hole and Multi-Hole design options. The R3 Ha Coated Acetabular Shells will be used with existing R3 Acetabular Liners and accessories and existing Smith & Nephew femoral heads and femoral stems.

V. Indications for 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.

VI. Comparison of Technological Characteristics with the Predicate Devices

The R3 HA Coated Acetabular Shells are technologically substantially equivalent to predicate devices in terms of intended use, material, design, mechanical performance and safety. The R3 HA Coated Acetabular Shells are manufactured from the same materials as the listed predicates. The shells are available in sizes with the same outer diameter. The locking mechanism is the same as for the predicate R3 Acetabular Shells. The R3 HA Coated Acetabular Shells are used with the same acetabular inserts that are used with the predicate R3 Acetabular Shells. Lastly, the asymmetric StikTite porous coating is the same as for the predicate Reflection 3 Acetabular Shells and the HA coating is the same as for the predicate Reflection Shells with HA.

The design characteristics of the subject system do not raise any new types of questions of safety or effectiveness.

K201701 510(k) Summary
R3 HA Coated Acetabular Shells

VII. Performance Data

The locking mechanism is the same as for the predicate R3 acetabular shell. Therefore, all testing previously conducted confirmed that the device should perform as intended. Testing conducted on the StikTite coating and hydroxyapatite according to FDA guidance confirmed that the coatings met applicable requirements.

Clinical data was not necessary to support a decision of substantial equivalence.

VIII. Conclusions

A review of the device indications, material composition, shell design, and technological characteristics confirmed that the R3 HA Coated Acetabular Shells are substantially equivalent to the predicate devices. While the R3 HA Coated Acetabular Shells are not identical to the predicate devices, comparisons of the subject and predicate devices confirmed that any differences in technological characteristics do not raise different questions of safety and effectiveness than the predicate device. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate devices. Therefore, it is concluded that the R3 HA Coated Acetabular Shells are substantially equivalent to the predicate devices.