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

October 31, 2019

Re: K191002
Trade/Device Name: OR3O Dual Mobility System
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 20, 2019
Received: September 23, 2019

Dear Mike Scott:

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)*
K191002

Device Name
OR3O Dual Mobility

Indications for Use *(Describe)*

Intended Use

The OR3O Dual Mobility System is intended for use in primary and revision total hip arthroplasty in skeletally mature patients.

Indications

- 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 hip joint fracture.

The OR3O Dual Mobility System is intended for single use only. The modular OR3O Liners and Inserts are to be implanted without bone cement.

Mating components may be indicated for use without 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 OR3O Dual Mobility System

I. SUBMITTER:

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

Phone: (901) 396-1633

Contact Person: Michael Scott
Date Prepared: October 29, 2019

II. DEVICE

Name of Device:	OR3O Dual Mobility System
Common Name:	Hip Prosthesis
Regulatory Class:	Class II
FDA Product Code:	LPH
Classification Name:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, (21 CFR888.3358)

III. PREDICATE DEVICE

Primary Predicate: POLARCUP Dual Mobility System - K110135 (S.E. 10/14/2011)
Predicate 2: REFLECTION Hip System – K071160 (S.E. 10/05/2007)
Predicate 3: BH Dual Mobility System - K171934 (S.E. 11/30/2017)
Predicate 4: OXINIUM DH Femoral Heads - K161233 (S.E. 12/14/2016)

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

IV. Device Description

The OR3O Hip System is a modular dual mobility implant system. The system consists of diffusion hardened, oxidized zirconium alloy liners with a highly polished inner surface of zirconia and a machined locking taper and backside of Zr-2.5Nb alloy. The locking taper and machined outside profile is designed to mate with a dedicated Ti 6Al 4V R3 or REDAPT Modular Press-fit acetabular shell with OD sizes 48mm to 74mm. For each assembled OR3O Liner and R3 and REDAPT Modular Shell size from 48mm to 74mm, a dedicated plastic insert made of highly crosslinked ultra-high-molecular-weight polyethylene (10Mrad irradiated and remelt-annealed UHMWPE (XLPE) according to ISO 5834-2/ASTM F648) is available. These can be combined with oxidized zirconium or CoCr alloy femoral heads of sizes 22mm (for size 48mm-52mm) and 28mm (for size 54mm-74mm). The final OR3O Dual Mobility construct will include an acetabular shell, an OXINIUM DH Liner, an XLPE Insert and a femoral head.

The purpose of this 510(k) submission is to add additional options of dual mobility implants to the Smith & Nephew collection of hip implants.

V. INDICATIONS FOR USE

Intended User

The OR3O Dual Mobility System is intended for use in primary and revision total hip arthroplasty in skeletally mature patients.

Indications

- 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 hip joint fracture.

The OR3O Dual Mobility System is intended for single use only. The modular OR3O Liners and Inserts are to be implanted without bone cement.

Mating components may be indicated for use without bone cement.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject OR3O Dual Mobility System implants have the same or similar intended use, fundamental scientific technology, materials, and indications for use as the following FDA cleared predicates: POLARCUP Dual Mobility System - K110135 (S.E. 10/14/2011)), REFLECTION Hip System – K071160 (S.E. 10/05/2007), BH Dual Mobility System - K171934 (S.E. 11/30/2017) and OXINIUM DH Femoral Heads - K161233 (S.E. 12/14/2016).

The subject device includes two new implant components to form a dual mobility concept where there are two articulating surfaces in the same joint space:

LINER

- The subject OR3O Dual Mobility System Liner uses an OXIDIZED DH Zirconium (OXINIUM DH) material with a highly polished inner surface similar to the predicate POLARCUP Dual Mobility inner surface - K110135 (S.E. 10/14/2011). The subject OXINIUM DH Liner has a locking taper and is designed to mate with an existing Smith & Nephew R3 (K092386 – S.E. 11/03/2009) or REDAPT Modular Shell - K182109 (S.E. 11/16/2018).
- The predicate device POLARCUP Dual Mobility System - K110135 (S.E. 10/14/2011) contains an XLPE Liner which is designed to articulate against a Stainless Steel POLARCUP Dual Mobility Shell.

INSERT

- The subject OR3O Dual Mobility Insert contains an XLPE Liner which is designed to articulate against the subject OR3O Dual Mobility Liner.

- The subject XLPE Material and Design are identical to the predicate BH Dual Mobility Material and Design - K171934 (S.E. 11/30/2017). Both the subject and predicate XLPE Inserts are intended to be used as an articulating component of a dual mobility system.

The subject OR3O Liner and OR3O Inserts are intended to be used with existing Smith & Nephew Acetabular Shells and Femoral Heads:

- Existing Acetabular Shells – The OR3O Dual Mobility System uses existing Smith & Nephew R3 Shells - K092386 (S.E. 11/03/2009) or Smith & Nephew REDAPT Modular Press-fit acetabular shells - K182109 (S.E. 11/16/2018).
- Existing Femoral Heads - The OR3O Dual Mobility System uses existing Smith & Nephew OXINIUM Femoral Heads K110101 (S.E. 04/11/2011) or Cobalt Chrome Femoral Heads – K963509 (S.E. 01/27/1997) and K963486 (S.E. 11/27/1996).

VII. PERFORMANCE DATA

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

Biocompatibility

The biocompatibility evaluation for the OR3O Dual Mobility Implants and Instruments 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 OR3O Dual Mobility Implants 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 OR3O Dual Mobility Liners are manufactured from Zr-2.5Nb alloy materials in accordance with the following ASTM standard: F2384- 10R16 Standard Specification for Wrought Zirconium-2.5Niobium Alloy for Surgical Implant Applications (UNS R60901).

The subject OR3O Dual Mobility Inserts are manufactured from identical polyethylene XLPE materials as the predicate device, in accordance with the following standards: ASTM F648-14 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants and ISO 5834-2 - Implants for surgery. Ultra-high-molecular-weight polyethylene. Moulded forms.

Instruments to support the OR3O Dual Mobility Implants have also been assessed for biocompatibility. The device specific implant OR3O Trial Liners have been manufactured from Radel PPSU (polyphenylsulfone) and the OR3O Trial Inserts are manufactured from Radel PPSU (polyphenylsulfone).

A biocompatibility report evaluation has been completed and summary rationales including Declaration of Conformity's have been provided for the subject OR3O Dual Mobility System.

Mechanical testing

Smith & Nephew has evaluated the subject OR3O Dual Mobility System to demonstrate substantial equivalence to the predicate POLARCUP Dual Mobility K110135 (S.E. 10/14/2011) and REFLECTION Hip System – K071160 (S.E. 10/05/2007) and determined that the subject devices do not represent a new worst case.

Biomechanical testing completed on the subject devices:

- Push Out Testing
- Torque to Failure Testing
- Lever-Out Testing
- Environmental Fatigue Testing
- Deformation Testing
- Wear Testing
- Pull-Out Testing
- Neck Impingement Testing
- Range of Motion
- Jump Distance

The subject OR3O Dual Mobility devices met the pre-determined acceptance criteria for each intended output. Therefore, design verification testing determined that the subject OR3O Dual Mobility System is substantially equivalent to the identified predicate devices.

Non-Pyrogenicity Endotoxin Testing

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 "Bacterial endotoxins – Test methods, routine monitoring and alternatives to batch testing".

VIII. CONCLUSIONS

Based on the verification evidence activities provided in this pre-market notification application, the subject OR3O Dual Mobility System is substantially equivalent to the legally marketed predicate devices POLARCUP Dual Mobility K110135 (S.E. 10/14/2011), REFLECTION Hip System K071160 (S.E. 10/05/2007), BH Dual Mobility K171934 (S.E. 11/30/2017), and OXINIUM DH Femoral Heads - K161233 (S.E. 12/14/2016).