October 27, 2023

Smith & Nephew, Inc.
Madison Padgett
Senior Regulatory Affairs Specialist
7135 Goodlett Farms Division
Cordova, Tennessee 38016

Re: K232667
Trade/Device Name: OR3O Dual Mobility Liners
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: August 31, 2023
Received: September 1, 2023

Dear Madison Padgett:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Limin Sun -S

Limin Sun, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232667

Device Name
OR3O Dual Mobility Liners

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.

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.

510(k) Summary
Smith & Nephew OR3O Dual Mobility Liners

I. SUBMITTER

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

Phone: (901) 456-8789

Contact: Madison Padgett
Date Prepared: October 27, 2023

II. DEVICE

Name of Device:	OR3O Dual Mobility Liners
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)
PREDICATE DEVICE	Primary Predicate: OR3O Dual Mobility System - K191002 (S.E. 10/31/2019) Predicate 2: OR3O Dual Mobility System - K220959 (S.E. 08/18/2022) Predicate 3: EPF-PLUS Cementless Press-Fit Acetabular Cup– K994146 (S.E. 12/11/2000)

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

III. Device Description

The OR3O Hip System was originally cleared via K191002 and K220959. The OR3O Hip System is a modular dual mobility implant system containing two distinct articulating surfaces. The hip system construct consists of a metal acetabular shell, diffusion hardened oxidized zirconium (OXINIUM DH) alloy liner, a cross linked polyethylene (XLPE) Insert and a femoral head.

The purpose of this premarket submission is to describe a proposed design modification isolated to the OR3O Dual Mobility Liners. The proposed modification is to increase the form tolerance of the articulation surface for the subject OR3O Dual Mobility Liners by 150% from 0.010mm to 0.025mm compared to the previously cleared OR3O Dual Mobility System - K191002 and K220959. The current form requirement is intended to limit the deviation of the articular surface to within 0.010mm of a perfect sphere.

The OR3O Dual Mobility Liner contains a machined locking taper and backside of Zr-2.5Nb alloy which is designed to press fit into modular acetabular shells. The 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).

IV. INDICATIONS FOR USE

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.

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject OR3O Dual Mobility System implants have the identical or similar intended use, fundamental scientific technology, materials, and indications for use as the following FDA cleared predicates: Smith & Nephew OR3O Dual Mobility System - K191002, Smith & Nephew OR3O Dual Mobility System - K220959 and EPF-PLUS Cementless Press-Fit Acetabular Cup– K994146.

The subject OR3O Liners are intended to be used within the cleared Smith & Nephew OR3O Dual Mobility System K191002 and K220959.

VI. PERFORMANCE DATA

The following performance data have previously been provided or are provided in support of the substantial equivalence determination.

Biocompatibility

The biocompatibility evaluation was previously 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 evaluation for the OR3O Dual Mobility Liner Implants, provided in predicate OR3O Dual Mobility System Submissions K191002 and K220959, remains applicable for the modified subject devices.

The subject OR3O Dual Mobility Implants are permanent implants and are 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).

Mechanical Testing

Smith & Nephew has evaluated the subject OR3O Dual Mobility System to demonstrate substantial equivalence to the identified predicate devices and determined that the subject devices do not represent a new worst case.

Biomechanical testing completed on the subject devices:

- Wear Testing

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

Non-Pyrogenicity Endotoxin Testing

Bacterial endotoxin testing was previously 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". The testing for the OR3O Dual Mobility Liner Implants, provided in predicate OR3O Dual Mobility System Submissions K191002 and K220959, remains applicable for the modified subject devices.

VII. CONCLUSIONS

Based on the verification evidence activities provided in this pre-market notification application, the subject modified OR3O Dual Mobility Liners utilized within the OR3O Dual Mobility System are substantially equivalent to the legally marketed predicate devices OR3O Dual Mobility System - K191002, OR3O Dual Mobility System - K220959, and EPF-PLUS Cementless Press-Fit Acetabular Cup– K994146.