October 7, 2024

Smith & Nephew, Inc.
Dana Hartlein
Senior Regulatory Affairs Specialist
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K242375
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: August 9, 2024
Received: August 9, 2024

Dear Dana Hartlein:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242375

Device Name

OR3O Dual Mobility System

Indications for Use *(Describe)*

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

Prepared on: 2024-10-07

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Smith & Nephew, Inc.
Applicant Address	1450 East Brooks Road Memphis TN 38116 United States
Applicant Contact Telephone	484-557-4768
Applicant Contact	Ms. Dana Hartlein
Applicant Contact Email	dana.hartlein@smith-nephew.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	OR3O Dual Mobility System
Common Name	Hip Prothesis
Classification Name	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulation Number	888.3358
Product Code(s)	LPH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K220959	OR3O Dual Mobility System	LPH
K191002	OR3O Dual Mobility System	LPH
K232667	OR3O Dual Mobility Liners	LPH
K211176	Smith & Nephew Hip Systems - MR Labeling and Design Chang	JDI

Device Description Summary 21 CFR 807.92(a)(4)

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 Traditional 510(k) is to add the MR safety information to the product labels and update the MR information within the package insert for the Smith & Nephew OR3O Dual Mobility System included within the scope of this 510(k). The subject OR3O Dual Mobility System is identical in design, technological characteristics, function, packaging, and sterilization to the commercially available predicate devices.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject OR3O Dual Mobility System has identical indications for use as the commercially available predicate cleared via the pre-market notifications listed above.

Technological Comparison 21 CFR 807.92(a)(6)

The subject Smith & Nephew OR3O Dual Mobility System is identical in design, material, technological characteristics, function of the devices, sterile packaging, and sterilization to the commercially available predicate devices cleared in K220959 (08/18/2022), K191002 (10/31/2019), and K232667(10/27/2023). The subject 510(k) is being submitted to add MR safety information to the product labels and update the MR information within the package insert of the OR3O Dual Mobility System previously cleared in K220959 (08/18/2022), K191002 (10/31/2019), and K232667(10/27/2023).

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject OR3O Dual Mobility System has identical indications for use as the commercially available predicate cleared via the pre-market notifications listed above.

Technological Comparison 21 CFR 807.92(a)(6)

The subject Smith & Nephew OR3O Dual Mobility System is identical in design, material, technological characteristics, function of the devices, sterile packaging, and sterilization to the commercially available predicate devices cleared in K220959 (08/18/2022), K191002 (10/31/2019), and K232667(10/27/2023). The subject 510(k) is being submitted to add MR safety information to the product labels and update the MR information within the package insert of the OR3O Dual Mobility System previously cleared in K220959 (08/18/2022), K191002 (10/31/2019), and K232667(10/27/2023).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Magnetic Resonance Imaging (MRI) compatibility testing was performed and the results of the testing performed were evaluated and used to generate recommended MRI safety labeling for the subject devices. Testing and evaluation were performed in accordance with the standards listed below:

1. Magnetically induced displacement force (ASTM F2052)

2. Magnetically induced torque (ASTM F2213)

3. Radiofrequency (RF) induced heating (ASTM F2182)

4. MR image artifact (ASTM F2119)

Based on the MRI assessment performed for the subject devices, the subject devices are MR Conditional and substantially equivalent to the predicate MRI 510(k) K211176.