January 19, 2022

Smith & Nephew, Inc.
Kayla Franklin
Regulatory Affairs Specialist I
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K211330
Trade/Device Name: R3 Large Head 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, JDI, LZO, MEH
Dated: December 17, 2021
Received: December 20, 2021

Dear Kayla Franklin:

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

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

510(k) Number *(if known)*

K211330

Device Name
R3 Large Head Liners

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.

The R3 Acetabular System is for single use only and is intended for cementless use.

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.

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510(k) Summary

Submitted by:	Smith & Nephew, Inc. Advanced Surgical Devices Division 7135 Goodlett Farms Parkway Cordova, Tennessee 38016
Date of Submission:	January 18, 2022
Contact Person:	Kayla Franklin, Regulatory Affairs Specialist I T (901) 800-3398 M (901) 325-2471
Name of Device:	R3 Large Head Liners
Common Name:	Acetabular Liners
Device Classification Name and Reference:	21 CFR 888.3358 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
Device Class:	Class II
Panel Code:	Orthopedics/87
Product Code:	LPH (primary), JDI, LZO, MEH
Predicate Device:	R3 Large Head Liners

Device Description:

The subject of this Traditional 510k is the R3 Large Head Liners 0 and 20-degree implants (28mm X 44mm – 36mm X 50mm). The R3 Large Head Liners are a line extension to the existing R3 Acetabular System. The R3 Large Head Liners were previously cleared for market via premarket notification K113848. The head size of the liners are being increased to include sizes 28mm X 44mm, 32mm X 46mm, and 36mm X 50mm (inner diameter and outer diameter, respectively) in 0 and 20-degree versions. The R3 Large Head Liners are intended for single use only. Similar head sizes have been cleared on R3 XLPE 36mm XLPE Liners via K092386, R3 40 and 44mm XLPE Liners via K093363, and REFLECTION 32mm X 50-52mm XLPE Acetabular Liner via K002747.

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.

The R3 Acetabular System is for single use only and is intended for cementless use.

Technological Characteristics

Device comparisons described in this premarket notification demonstrate that the subject devices, R3 Large Head Liners 0 and 20-degree implants (28mm X 44mm – 36mm X 50mm), are substantially equivalent to the below listed legally marketed predicate devices (**Table 6.1**) with regard to intended use, indications for use, design, material and performance characteristics. Identical to that of the predicate R3 Large Head Liners cleared via premarket notification K113848 (S.E. 04/27/12), the subject R3 Large Head 0 and 20-degree implant liners (28mm X 44mm – 36mm X 50mm) are also made from Cross Linked Polyethylene (XLPE), undergo the same manufacture process, have the same surface finish, and the same locking mechanism. The subject and predicate R3 liners also have similar inner and outer diameters, as well as being offered in similar design options. Additionally, the predicate R3 36mm XLPE Liners, K092386 (S.E. 11/03/09) and predicate R3 40 and 44mm XLPE Liners, K093363 (S.E. 01/26/10) have similar head sizes to that of the subject R3 Large Head liners.

Substantial Equivalence Information

The overall design, materials, and indications for use for the R3 Large Head Liners 0 and 20-degree implants (28mm X 44mm – 36mm X 50mm) are substantially equivalent to the predicate devices listed in **Table 6.1** below. In addition to the similarities stated above in the Technological Characteristics, the subject devices also utilize the same sterilization method as their predicates. While the subject devices are not identical in design to the predicate devices, any differences that may exist between the subject device and the predicates identified below do not significantly affect the safety or effectiveness of the device.

Table 6.1: Predicate Devices

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	R3 XLPE Liners (Primary Predicate)	K113848	04/27/12
Smith & Nephew, Inc.	R3 36mm XLPE Liners	K092386	11/03/09
Smith & Nephew, Inc.	R3 40 and 44mm XLPE Liners	K093363	01/26/10
Smith & Nephew, Inc.	REFLECTION 32mm X 50-52mm XLPE Acetabular Liner	K002747	12/15/00

Performance Testing

To further support a determination of substantial equivalence, non-clinical bench (mechanical) testing was performed on the R3 Large Head Liners 0 and 20-degree implants (28mm X 44mm – 36mm X 50mm). A review of the testing indicates that the R3 Large Head Liners 0 and 20-degree implants (28mm X 44mm – 36mm X 50mm) are substantially equivalent to predicate devices listed in **Table 6.1** above.

The following tests were used as a basis for the determination of substantial equivalence. The testing included the following:

- Lever-Out
- Push-Out
- Torque-Out
- Fatigue
- Post Fatigue Push-Out
- Biocompatibility
- Impingement
- Range of Motion
- Wear

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.

Conclusion

In summary, this 510(k) Premarket Notification is being submitted to request clearance for the R3 Large Head Liners 0 and 20-degree implants (28mm X 44mm – 36mm X 50mm). Based on the similarities to the predicate devices and a review of the bench testing, the subject devices are substantially equivalent to the commercially available predicate devices listed above.