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

November 19, 2018

Re: K182535
Trade/Device Name: R3 Anteverted 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: MBL
Dated: October 23, 2018
Received: October 24, 2018

Dear Meenakshi Gupta:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel S. Ramsey -S
2018.11.19 16:51:55 -05'00'

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K182535

Device Name
R3 Anteverted 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(K) SUMMARY

| | |
|---|---|
| **Submitted by:** | Smith & Nephew, Inc.<br>Advanced Surgical Devices Division<br>7135 Goodlett Farms Parkway<br>Cordova, Tennessee 38016 |
| **Date of Submission:** | September 13, 2018 |
| **Contact Person:** | Meenakshi Gupta, Sr. Regulatory Affairs Specialist<br>T (901) 399-6139<br>F (901) 721-2748 |
| **Name of Device:** | R3◊ Anteverted 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:** | Orthopaedics/87 |
| **Product Code:** | MBL |
| **Predicate Device:** | Primary Predicate-R3 XLPE Liners-K113848<br>Predicate 2-R3 XLPE Liners-K093363<br>Predicate 3-REFLECTION Acetabular System-K920430<br>Reference Predicate-R3 XLPE Anteverted Liners-K102370<br><br>The predicate devices have not been subject to a design related recall. |

**Device Description:**

The subject of this Special 510(k) is the R3◊ Anteverted Liners. The subject R3 Anteverted Liners are a line extension to the R3 XLPE Liners that were cleared under premarket notifications K113848 and K093363. The R3 Anteverted Liners have same overall design, indication for use and material as the predicate R3 XLPE liners.

The subject R3 Anteverted Liners feature a 20° anteverted, or “face changing”, entry angle to the articulating surface (Inner diameter). Also, a variable angle chamfer/bevel was added on the rim of the liner. The R3 Anteverted Liners have +4mm lateralized inside Diameter, 20˚ angle, and identical locking mechanism as the predicate R3 XLPE Liners, cleared under K113848 and K093363.

The R3 Anteverted Liners are available with Inner diameter (ID) sizes 28, 32, 36, 40 and 44mm and the Outer Diameter (OD) sizes ranging from 44 to 76-80mm.The R3 Anteverted Liner is manufactured from 10MRAD Cross-linked Polyethylene (XLPE) confirming to ASTM F648, as the predicate R3 XLPE Liners cleared under a premarket notification K113848 and K093363. The R3 Anteverted Liners are provided sterile and is intended for single use only.

**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.

The above indication for use for the subject device, is identical to the R3 XLPE Liner cleared under K113848 and K093363, the REFLETION Acetabular System (K920430) and R3 XLPE Anteverted Liners (K102370).

**Comparison of Technological Characteristics with the Predicate Device**

**Intended Use:** The proposed R3 Anterverted Liners have identical Intended use as the predicate R3 XLPE Liners

**Indication for Use:** The proposed R3 Anterverted Liners have identical Indication for Use as the predicate R3 XLPE Liners

**Materials:** The proposed R3 Anterverted Liners are manufactured by same material and manufacturing process as the predicate R3 XLPE Liners

**Design Features:** The proposed R3 Anterverted Liners have overall same design features as the predicate R3 XLPE Liners.

**Sterilization:** The proposed R3 Anterverted Liners and predicate R3 XLPE Liners are provided sterile by Ethylene Oxide for single-use.

Therefore, the technological characteristics of the subject device are the similar to the technological characteristics of the predicate device R3 XLPE Liners cleared under K113848 and K093363.

**Substantial Equivalence Information**

The overall design, materials, and indications for use for R3 Anteverted Liners are substantially equivalent to the following commercially available predicate devices.

**Table: Predicate Devices**

| Manufacturer | Description | Submission Number | Clearance Date |
|---|---|---|---|
| Smith & Nephew, Inc. | R3 XLPE Liner | K113848 (Primary) | 04/27/2012 |
| Smith & Nephew, Inc. | R3 XLPE Liner | K093363 | 01/26/2010 |
| Smith & Nephew, Inc. | Reflection Acetabular System | K920430 | 07/21/1992 |
| Smith & Nephew, Inc. | R3 XLPE Anteverted Liners | K102370 | 01/19/2011 |

**Performance Testing**

To further support a determination of substantial equivalence, non-clinical bench (mechanical) testing were conducted on the R3 Anteverted Liners. A review of the mechanical data and the technical memo, indicates that the R3 Anteverted Liners are substantially equivalent to predicate devices listed in the Table above.

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

- Push-in
- Push-out
- Lever-out
- Torque to Failure
- Finite Element Analysis
- Range of Motion Analysis
- Poly thickness comparison
- Biocompatibility

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**

As previously noted, this special 510(k) Premarket Notification is being submitted to request clearance for the R3 Anteverted Liners. Based on the similarities to the predicate devices and a review of the mechanical testing performed, the subject device is substantially equivalent to the commercially available predicate devices listed above.