October 1, 2021

Smith & Nephew, Inc.
Brad Sheals
Senior Regulatory Affairs Manager
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K211221
Trade/Device Name: Porous Patella and Porous Tibia Baseplate
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: September 9, 2021
Received: September 10, 2021

Dear Brad Sheals:

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,

Ting Song, Ph.D., R.A.C.
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)*

K211221

Device Name
Porous Patella and Porous Tibia Baseplate

Indications for Use *(Describe)*
Total knee components are indicated for:

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. The posterior-stabilized knee system is designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

LEGION Porous CR Narrow Femoral Components are indicated for use without bone cement and are single use devices.

The Porous Patella and the Porous Tibia Baseplate are indicated for use with or without bone cement, and are single use devices.

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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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Smith+Nephew

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	September 09, 2021
Contact Person and Address:	Mr. Brad Sheals, MS Senior Regulatory Affairs Manager Mobile: (901) 288-7141
Secondary Contact Person and Address:	Mrs. Michelle Huettner, RAC Regulatory Affairs Director Mobile: (765) 426-6070
Name of Device:	Porous Patella and Porous Tibia Baseplate
Common Name:	Patella and Tibia Baseplate
Device Classification Name and Reference:	21 CFR 888.3565 - Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis (Primary classification) 21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	MBH and JWH
Predicate Device:	Porous Patella Predicate – Triathlon® Tritaniurn® Metal-Backed Patella K132624 (Primary predicate) GENESIS II Total Knee System- Patella K951987 Reference predicate devices include- ZUK™ UHMWPE Articular Surface K033363 REDAPT CONCELOC Fully Porous Cup K181366 Porous Tibia Baseplate Predicate – LEGION Porous + HA Tibial Baseplates K100897 (Primary predicate) JOURNEY Non-Porous Tibia Baseplates K042515 Genesis II Porous Tibial Trays and Revision Knee System K953274

Device Description

The subject Porous Patella is designed to be implanted with or without the use of bone cement for a total knee replacement. The Porous Patella will be made of UHMWPE and Ti-6Al-4V. The metal bone contacting surface and 3 pegs will be made from Ti-6Al-4V, which will be porous, and the bearing surface will be UHMWPE. The bone contacting porous structure will be made of CONCELOC, a material formerly cleared as part of the REDAPT CONCELOC Fully Porous Cup, K1813266. The UHMWPE will be direct compression molded on to the Ti-6Al-4V metal back. The subject Porous Patella will be designed as oval and round resurfacing patellae. The subject device will be press fit into the bone with 3 pegs for initial fixation and provided in various sizes, 26mm-41mm. As a reference, the bearing surface profile of this subject Porous Patella is identical to the Smith & Nephew Genesis II Patella, which was cleared under K042515.

The subject Porous Tibia Baseplate is designed to be implanted with or without the use of bone cement. The Porous Tibia Baseplate is made of Ti-6Al-4V and includes a porous ingrowth surface on the distal face of the implant. The proximal face of the implant includes locking mechanism, dimensions, and size options identical to Smith & Nephew's Journey cemented tibial implant cleared under K121443. The distal side of the implant has a central stem, two large posterior-directed fins, and two smaller anterior-directed fins. There are also two tibial lugs on the anterior half of the implant, one on each of the medial and lateral side of the stem. The subject device includes the same stem length for all sizes, though the fin sizes and locations of the lugs vary between sizes. The subject tibia baseplate includes multiple sizes in both left and right hand versions.

Indication for Use:

Total knee components are indicated for:

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. The posterior-stabilized knee system is designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

LEGION Porous CR Narrow Femoral Components are indicated for use without bone cement and are single use devices.

The Porous Patella and the Porous Tibia Baseplate are indicated for use with or without bone cement, and are single use devices.

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Technological Characteristics

A review of the technological characteristics indicates that the subject Porous Patella and the subject Porous Tibia Baseplate are equivalent to existing, legally marketed predicate devices with regards to mechanical performance (e.g. Mechanical testing and assessments) and that there are no new issues related to the safety and effectiveness of the subject devices. Clinical data was not needed to support the safety and effectiveness of the subject devices.

Substantial Equivalence Information

The subject devices are identical in function, intended use, indications for use, and equivalent material composition, and very similar in overall design to the predicate devices listed in the following tables, **5.1** and **5.2**.

Table 5.1: Substantially Equivalent Predicate(s)- Porous Patella

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew (Primary Predicate)	GENESIS II Total Knee System-Patella	K951987	08/22/1995
Stryker Orthopaedics	Triathlon® Tritaniurn® Metal-Backed Patella	K132624	11/26/2013

Reference porous patella predicate devices within this submission included the ZUK™ UHMWPE Articular Surface (K033363, S.E.01/16/2004) and REDAPT CONCELOC Fully Porous Cup (K181366, S.E. 09/24/2018).

Table 5.2: Substantially Equivalent Predicate(s)- Porous Tibia Baseplate

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew (Primary Predicate)	GENESIS POROUS TIBIAL TRAYS & REVISION KNEE SYSTEM	K953274	02/05/1996
Smith & Nephew	LEGION Porous + HA Tibial Baseplates	K100897	05/13/2010
Smith & Nephew	Journey Non-Porous Tibia Baseplate	K042515	03/14/2005

Performance Testing:

To further support a determination of substantial equivalence, Mechanical testing and/or assessments was utilized. A review of the leveraged data indicates that the subject Porous Patella and Porous Tibia Baseplate are substantially equivalent to one or more of the previously cleared predicate devices listed in **Tables 5.1** and **5.2** above. The following performance testing in **Table 5.3** was used as a basis for the determination of substantial equivalence.

Table 5.3: Benchtop Performance Testing Strategy

Porous Patella	Porous Tibia Baseplate
• Tensile Strength • Shear Strength • Peg Shear Strength • Shear Fatigue • Durability testing • Contact Area and Contact Stresses • Resistance to Subluxation • Surface Pore Diameter • Mean Coating Thickness • Roughness • Tensile Properties • Impact Resistance • Average Porosity • Mean Void Intercept Length • Mechanical Testing of Compression molded Polyethylene • Nitric Passivation of UHMWPE	• Finite Element Analysis for Worst Case Fatigue • Unsupported Baseplate Fatigue • Cement Adhesion • Intra-plate variability • Chemical composition of substrate • Surface Pore Diameter • Mean coating thickness • Mean void intercept length (MVIL) • Average porosity (mean volume percent voids) • Weld diameter or area • Microstructure • Roughness • Static Shear Strength- baseplate pegs • Shear fatigue Strength- baseplate pegs • Shear fatigue- baseplate porous coating/substrate • Tensile attachment Strength • Tensile properties of substrate • Inter-plate variability • Abrasion Resistance

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 Traditional 510(k) Premarket Notification is being submitted to request clearance for the Porous Patella and Porous Tibia Baseplate. Based on the similarities to the predicate devices, the subject devices are substantially equivalent to the commercially available cleared predicate devices listed above.