July 26, 2022

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

Re: K221939
Trade/Device Name: Cemented Round Patella with JRNY Pegs
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: June 30, 2022
Received: July 1, 2022

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 (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.
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)*

K221939

Device Name

Cemented Round Patella with JRNY Pegs

Indications for Use *(Describe)*

Total Knee components are indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis; failed osteotomies, unicompartmental replacement, or total knee replacement. Posterior stabilized knee systems are 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. Constrained knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are incompetent. Hinge knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are absent or incompetent.

The Smith & Nephew, Inc. Cemented Round Patellae with JRNY Pegs are indicated for use with cement and are single use devices.

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

510(k) Summary Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 7135 Goodlett Farms Parkway Cordova, Tennessee 38016
Date of Summary:	July 21, 2022
Primary Contact Person:	Madison Padgett, Regulatory Affairs Specialist II Phone: (901) 456-8789
Secondary Contact Person	Michelle Huettner, Director, Regulatory Affairs Phone: (765) 426-6070
Name of Device:	Cemented Round Patella with JRNY Pegs
Common Name:	Patella Component
Device Classification Name and Reference:	21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	JWH – Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer
Predicate Device:	Primary Predicate – K951987 – GENESIS II Total Knee System - Patella (S.E. 8/22/1995) - JWH Secondary Predicate – K042515 – Smith & Nephew, Inc. High Performance Knee - Patella (S.E. 3/14/2005) - JWH The predicate devices have not been subject to a design related recall.

Device Description

The subject of this Special 510(k) is the Cemented Round Patellae with JRNY Pegs. The subject Cemented Round Patella with JRNY Pegs are patella components, and a line extension of the GENESIS II Resurfacing Patellae cleared under the GENESIS II Total Knee System premarket notification K951987 (S.E. 8/22/1995). The subject devices were modified by incorporating the identical patella peg and cement pocket geometry from the JOURNEY BCS Resurfacing Patellae, cleared under Smith & Nephew, Inc. High Performance Knee premarket notification K042515 (S.E. 3/14/2005) respectively.

The subject Cemented Round Patellae with JRNY Pegs have a size range of 26, 29, 32, 35, 38, and 41mm with thicknesses range of 7.5mm and 9.0mm. The Cemented Round Patellae with JRNY Pegs are manufactured from Ultra-High Molecular Weight Polyethylene (UHMWPE), conforming to ASTM F648 (FDA Recognition Number 8-569), and 316 L Stainless Steel, conforming to ASTM F138 (FDA Recognition Number 8-542), identical to the predicate devices GENESIS II Resurfacing Patellae (K951987, S.E. 8/22/1995) and JOURNEY BCS Resurfacing Patellae (K042515, S.E. 3/14/2005).

Indication for Use:

Total Knee components are indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis; failed osteotomies, unicompartmental replacement, or total knee replacement. Posterior stabilized knee systems are 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. Constrained knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are incompetent. Hinge knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are absent or incompetent.

The Smith & Nephew, Inc. Cemented Round Patellae with JRNY Pegs are indicated for use with cement and are single use devices.

Technological Characteristics

A review of the technological characteristics indicates that the subject Cemented Round Patellae with JRNY Pegs would be expected to perform substantially equivalent to, legally marketed predicate devices with regards to mechanical performance and that there are no new potential risks 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 substantially equivalent to the predicate devices listed in the following table in function, intended use, indications for use, design, and material composition.

Table 5.1: Substantially Equivalent Predicates

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	GENESIS II Total Knee System - Patella	K951987	8/22/1995
Smith & Nephew, Inc.	Smith & Nephew, Inc. High Performance Knee - Patella	K042515	3/14/2005

Performance Testing:

A review of the leveraged mechanical data indicates that the subject Cemented Round Patellae with JRNY Pegs are substantially equivalent to one or more of the previously cleared predicate devices listed in **Table 5.1** above. The following design features were evaluated in comparison to predicate devices GENESIS II Resurfacing Patellae (K951987 S.E. 8/22/1995) and JOURNEY BCS Resurfacing Patellae (K042515, S.E. 3/14/2005) to determine the substantial equivalence:

- Peg Geometry
- Peg Location
- Pocket Geometry

Bacterial endotoxin testing for the representative worst-case device has been leveraged for the subject Cemented Round Patellae with JRNY Pegs 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 (FDA Recognition Number 14-541).

Conclusion

As previously noted, this Special 510(k) Premarket Notification is being submitted to request clearance for the Cemented Round Patellae with JRNY Pegs. Based on the similarities to the predicate devices and rationale to support substantial equivalence, the subject devices are substantially equivalent to the commercially available predicate devices listed in **Table 5.1**.