August 17, 2021

Smith & Nephew, Inc.
Kayla Franklin
Regulatory Affairs Specialist I
1450 East Brooks Rd
Memphis, Tennessee 38116

Re: K211671
Trade/Device Name: Journey II Mid-Level Tibial Inserts
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: August 6, 2021
Received: August 9, 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211671

Device Name
Journey II Mid-Level Tibial Inserts

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.

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:	August 17, 2021
Contact Person:	Kayla Franklin, Regulatory Affairs Specialist I T (901) 800-3398 M (901) 325-2471
Name of Device:	Journey II Mid-Level Tibial Inserts
Common Name:	Knee Prosthesis
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:	Orthopedics/87
Product Code:	JWH
Predicate Device:	Journey II BCS XLPE Articular Inserts, Journey II BCS Constrained Articular Inserts, Journey II CR XLPE Articular Inserts, and Journey II Inserts XLPE Deep Dished

Device Description:

The purpose of this Special 510(k) is to notify FDA of our intent to market the Smith & Nephew Journey II Mid-Level Tibial Inserts. The Smith & Nephew Journey II Mid-Level Tibial Inserts consist of Journey II Articular Stabilized XLPE Articular Inserts Size 1-8 Right and Left (9mm-21mm) and Journey II Medial Dished XLPE Articular Inserts Size 1-8 Right and Left (9-18mm).

The Smith & Nephew Journey II Articular Stabilized XLPE Articular Inserts Size 1-8 Right and Left (9-21mm) are line additions to the existing Journey II BCS XLPE Articular Inserts Size 1-8 Right and Left (9-21mm) and the Journey II BCS Constrained Articular Inserts Size 1-8 Right and Left (9-25mm) cleared via premarket notification K111711 and K140555, respectively.

The Smith & Nephew Journey II Medial Dished XLPE Articular Insert Size 1-8 Right and Left 9-18mm are line additions to the existing Journey II CR XLPE Articular Insert Size 1-8 Right and Left (9-18mm) and the Journey II Insert XLPE Deep Dished Right and Left Size 1-8 (9-21mm) cleared via premarket notification K121443 and K113482, respectively.

The Journey II Articular Stabilized XLPE Articular Inserts offers total knee arthroplasty patients with soft tissue structures on the lateral side of the knee that have increased laxity an additional level of conformity to provide needed stability. The Journey II Articular Stabilized XLPE Articular Inserts provide additional posterolateral A/P stability compared to Journey II BCS but without the varus/valgus constraint provided by the more robust Journey II BCS Constrained post.

The Journey II Medial Dished XLPE Articular Inserts offers total knee arthroplasty patients having insufficient posterior cruciate ligament (PCL) function an additional level of medial anterior/posterior constraint over existing Journey II CR XLPE Articular Inserts while

seeking to promote improved kinematics and lateral femoral rollback compared to the more constraining Journey II Inserts XLPE Deep Dished.

Indications 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.

Technological Characteristics

Device comparisons described in this premarket notification demonstrate that the subject devices, Journey II Mid-Level Tibial Inserts, are substantially equivalent to the below listed legally marketed predicate devices with regard to intended use, indications for use, similar design, material and performance characteristics.

Substantial Equivalence Information

The overall design, materials, and indications for use for Journey II Mid-Level Tibial Inserts are substantially equivalent to the predicate devices listed in **Table 6.1** below.

Table 6.1: Predicate Devices

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Journey II BCS XLPE Articular Inserts Size 1-8 Right and Left (9-21mm)	K111711	09/16/2011
Smith & Nephew, Inc.	Journey II BCS Constrained Articular Inserts Size 1-8 Right and Left (9-25mm)	K140555	05/29/2014
Smith & Nephew, Inc.	Journey II CR XLPE Articular Insert Size 1-8 Right and Left (9-18mm)	K121443	08/13/2012

Smith & Nephew, Inc.	Journey II Insert XLPE Deep Dished Right and Left Size 1-8 (9-21mm)	K113482	02/27/2012

Preclinical Testing

To further support a determination of substantial equivalence, various types of preclinical testing were conducted on the subject, implantable devices in comparison against one or more of the previously cleared predicate devices described in **Table 6.1** above. A review of the testing indicates that the Journey II Mid-Level Tibial Inserts are substantially equivalent to predicate devices listed in above. The specific types of pre-clinical testing include:

- **Finite Element Analysis of the Post Strength of the Journey II Articular Stabilized (AS) Insert as Compared to the Journey II Bi-Cruciate Stabilized (BCS) Insert (OR-20-140) -** The primary goal of this study was to evaluate the structural strengths of the Journey II Articular Stabilized (AS) Insert Implants. Maximum principal stresses were calculated using Finite Element Analysis (FEA).

- **Anterior/Posterior (A/P) 30° Fatigue Testing of the Journey II Articular Stabilized (AS) Size 5-6 Tibial Insert (OR-21-058) –** The purpose of this study was to evaluate the anterior/posterior (A/P) fatigue strength of the Journey II Articular Stabilized (AS) Insert as compared to the Journey II Bi-Cruciate Stabilized (BCS) Insert.

- **Tibiofemoral Constraint Testing According to ASTM F1223-20 of the Journey BCS Femoral in Conjunction with the Journey II Articular Stabilized (AS) Insert as Compared to the Journey II BCS Insert (OR-21-059) -** The purpose of this study was to evaluate the anterior/posterior (A/P) draw constraint and flexion rotary laxity (R/L) torsional constraint for the

Journey II Articular Stabilized (AS) insert as compared to the Journey II BCS insert.

- **Tibiofemoral Contact Area Analysis of the Size 1 Journey II BCS Femoral Component on Size 1-2 Journey II Articular Stabilized (AS) Inserts from 0° to 160° of Angulation (OR-21-060) -** The purpose of this study was to evaluate the tibiofemoral contact area of the Journey II BCS femoral component with the Journey II Articular Stabilized (AS) Inserts at Internal/External (I/E) rotation angles. These results were compared to the previously evaluated results of the tibiofemoral contact area of the Journey II BCS femoral with the Journey II BCS inserts.

- **Tibiofemoral Contact Area Analysis of the Size 1 Journey II CR Femoral Component on Size 1-2 Journey II Medial Dished (MD) Inserts from 0° to 160° Angulation (OR-21-061) -** The purpose of this study was to evaluate the tibiofemoral contact area of the Journey II CR femoral component with the Journey II Medial Dished (MD) Inserts at Internal/External (I/E) rotation angles. These results were compared to the previously evaluated results of the tibiofemoral contact area of the Journey II CR femoral with the Journey II CR Standard and Deep Dish Inserts.

- **Tibiofemoral Constraint Testing of the Journey II CR Femoral in Conjunction with the Journey II Medial Dished (MD) Insert (OR-21-062) -** The purpose of this study was to evaluate the anterior/posterior (A/P) draw, medial/lateral (M/L) constraint, and rotary laxity (R/L) torsional constraint of flexion for the Journey II Medial Dished (MD) insert as compared to the Journey II CR insert and the Journey II Deep Dished insert.

Conclusion

In summary, this Special 510(k) Premarket Notification is being submitted to request clearance for the Journey II Mid-Level Tibial Inserts. Based on the similarities to the predicate devices, the subject devices are product derivatives and substantially equivalent to the commercially available predicate devices listed above.