October 28, 2022

Smith+Nephew, Inc
Lilian Hren
Sr. Regulatory Affairs Specialist
1450 Brooks Rd
Memphis, Tennessee 38116

Re: K222653
Trade/Device Name: JOURNEY II UK™ and ENGAGE™ Cementless Partial Knee System
Regulation Number: 21 CFR 888.3535
Regulation Name: Knee Joint Femorotibial (Uni-Compartmental) Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: NJD, HSX
Dated: August 31, 2022
Received: September 1, 2022

Dear Lilian Hren:

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.

Submission Number *(if known)*

K222653

Device Name

JOURNEY II UK™ and ENGAGE™ Cementless Partial Knee System

Indications for Use *(Describe)*

Indications for JOURNEY II Unicompartmental Knee System:
Unicompartmental knee implants are indicated for restoring either compartment of a knee that has been affected by the following:
- Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- Correction of functional deformity;
- Revision of previous arthroplasty procedures;
- Treatment of fractures that are unmanageable using other techniques.

Unicompartmental knee implants are single-use only and intended for implantation only with bone cement.

Indications for ENGAGE™ Partial Knee System:
The ENGAGE™ Partial Knee System is intended for medial unicompartmental knee arthroplasty to treat one or more of the following conditions:
- Moderately disabling joint disease of the knee resulting from painful osteo- or post-traumatic arthritis.
- Revision of previous unsuccessful surgical procedures including prior unicompartmental knee arthroplasty
- As an alternative to tibial osteotomy in patients with Unicompartmental osteoarthritis.

The femoral component and tibial tray are intended for cementless or cemented fixation. The porous surfaces of both the femoral and tibial tray components provide biological fixation when used in a cementless application. When the tibial tray is implanted without the use of bone cement, the tibial anchor should be used. When the tibial tray is implanted with bone cement, the tibial anchor should not be used.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Smith+Nephew

Section 05 – 510(k) Summary

Submitted by:	Smith+Nephew, Inc Orthopaedic Division 1450 Brooks Rd Memphis, Tennessee 38116
Data of Summary:	October 28, 2022
Contact Person:	Lilian Hren Sr. Regulatory Affairs Specialist M: 901.558.8200 lilian.hren@smith-nephew.com
Name of Device:	JOURNEY II UK™ and ENGAGE™ Cementless Partial Knee System
Common Name:	Knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis
Classification Name:	Prosthesis, Knee, Femorotibial, Unicompartmental/Unicondylar, Uncemented, Porous-Coated, Metal/Polymer
Regulation Number:	888.3535
Product Code:	NJD, HSX
Device Class:	Class II
Panel code:	Orthopaedics/87

Predicate Device:	Primary Predicate: Engage™ Partial Knee System - K190439 Secondary Predicate: Journey II Unicompartmental Knee System (Journey II UK) –K190085 Journey II Unicompartmental Knee System (Journey II UK) – K191211

Device Description

The purpose of this Traditional 510(k) submission is to seek FDA clearance of the existing devices ENGAGE™ Partial Knee System and JOURNEY II Unicompartmental Knee System components to be used in various combinations to create a hybrid unicompartmental knee system.

No new or modified knee implant components or new device-specific instruments are being introduced as a result of this filing where, ENGAGE™ Partial Knee System used with JOURNEY II Unicompartmental Knee System, are both FDA 510(k) cleared as follows: K190439 (S.E. 11/21/2019) - ENGAGE™ Partial Knee System; K191211 (S.E. 07/25/2019) and K190085 (S.E. 02/11/2019) - JOURNEY II Unicompartmental Knee System.

Together with the existing Smith+Nephew knee implants, these devices will be marketed under the trade name JOURNEY II UK™ and ENGAGE™ Cementless Partial Knee System. Only the use of the respective unicompartmental knee femoral/tibial devices in a hybrid device combination is changing. As a result of the acquisition of ENGAGE Surgical, ENGAGE product line in the US. Smith+Nephew now has responsibility for the ENGAGE™ Partial Knee System and has been listed as the specification developer and the complaint file establishment. The JOURNEY II UK™ and ENGAGE™ Cementless Partial Knee System is an implant system intended for unicompartmental knee arthroplasty. The subject device is a unicondylar femoral and tibial implant set in a hybrid system that incorporates JOURNEY II Unicompartmental Knee System with ENGAGE components, where the JOURNEY II Unicompartmental Knee System components are cemented and the ENGAGE components are cementless. To better fit the patient, the system consists of various sizes for the femoral and tibial components.

JOURNEY II Unicompartmental Knee System (JOURNEY II UK) components:

The subject JOURNEY II UK Femoral implant is available in ten sizes each in left medial/right lateral and right medial/left lateral side (hand) configuration. This component

is manufactured from Zr-2.5Nb alloy materials in accordance with the following ASTM standard F2384 Standard Specification for Wrought Zirconium-2.5Niobium Alloy for Surgical Implant Applications (UNS R60901). This material is identical to material that has been in previous Smith & Nephew Knee System submissions including the predicate K191211 (S.E. 07/25/2019) and K190085 (S.E. 02/11/2019) - JOURNEY II Unicompartmental Knee System.

The subject JOURNEY II UK Articular Insert is available in medial and lateral configurations for use with the corresponding baseplate and is symmetric for use in either right or left hand. This component is manufactured from XLPE materials in accordance with the ASTM standard F648 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants (FDA Recognition Number 8-569). This material is identical to material that has been in previous Smith & Nephew Knee System submissions including the predicate K191211 (S.E. 07/25/2019) and K190085 (S.E. 02/11/2019) - JOURNEY II Unicompartmental Knee System.

The subject JOURNEY II UK Baseplate is available in ten sizes of implant with a medial primary / lateral secondary use offered in both left and right handedness (listed henceforth as “medial primary”), and eight sizes of implant with a lateral primary / medial secondary use offered in both left and right handedness (listed henceforth as “lateral primary”). Each is expected to be used in its primarily listed compartment most often but is designed for use in either medial or lateral compartments. The component is manufactured from Ti-6Al-4V materials in accordance with the ASTM standard F1472 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400) (FDA Recognition Number 8-555). This material is identical to material that has been in previous Smith & Nephew Knee System submissions including the predicate K191211 (S.E. 07/25/2019) and K190085 (S.E. 02/11/2019) - JOURNEY II Unicompartmental Knee System.

ENGAGE™ Partial Knee System components:

The subject ENGAGE Porous Coated Femoral is available in eight sizes. This component is manufactured from CoCr Alloy materials in accordance with the ASTM standard F75 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075) (FDA Recognition Number 8-498). and is coated with a rough asymmetrical sintered bead coating composed of Cobalt Chromium Alloy ASTM standard F75 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075) (FDA Recognition Number 8-498). This material is identical to material that has been in previous Smith & Nephew Knee System submissions including the predicate K190439 (S.E. 11/21/2019) - ENGAGE™ Partial Knee System.

The subject ENGAGE Tibial Insert is available in four thicknesses. This component is manufactured from UHMWPE materials in accordance with the ASTM standard F648 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants (FDA Recognition Number 8-569). This material is identical to material that has been in previous Smith & Nephew Knee System submissions including the predicate K190439 (S.E. 11/21/2019) - ENGAGE™ Partial Knee System.

The subject ENGAGE Coated Tibial Tray is available in six sizes and includes pegs and an engineered porous surface that is intended for biological fixation when used without bone cement and it possesses a locking mechanism to retain the UHMWPE tibial insert. The tibial-femoral articulation is non-constrained. This component is manufactured from Ti-6Al-4V materials in accordance with the ASTM standard F3001 Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion and includes an engineered porous surface also composed of Titanium Alloy (ASTM F3001) (FDA Recognition Number 8-439) on the bone-contacting surface. This material is identical to material that has been in previous Smith & Nephew Knee System submissions including the predicate K190439 (S.E. 11/21/2019) - ENGAGE™ Partial Knee System.

The subject ENGAGE Tibial Anchor Stem is available in three lengths and provides supplemental fixation of the tibial tray when implanted without bone cement. This component is manufactured from Ti-6Al-4V ELI materials in accordance with the ASTM standard F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401) (FDA Recognition Number 8-377). This material is identical to material that has been in previous Smith & Nephew Knee System submissions including the predicate K190439 (S.E. 11/21/2019) - ENGAGE™ Partial Knee System.

The instrumentation required will consist of femoral and tibial instruments which are used to make appropriate resections to prepare the femur/tibia for the implants.

Indications for Use:

Indications for JOURNEY II Unicompartmental Knee System:

Unicompartmental knee implants are indicated for restoring either compartment of a knee that has been affected by the following:

- Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;

- Correction of functional deformity;

- Revision of previous arthroplasty procedures;

- Treatment of fractures that are unmanageable using other techniques.

Unicompartmental knee implants are single-use only and intended for implantation only with bone cement.

Indications for ENGAGE™ Partial Knee System:

The ENGAGE™ Partial Knee System is intended for medial unicompartmental knee arthroplasty to treat one or more of the following conditions:

- Moderately disabling joint disease of the knee resulting from painful osteo- or post-traumatic arthritis.

- Revision of previous unsuccessful surgical procedures including prior unicompartmental knee arthroplasty

- As an alternative to tibial osteotomy in patients with Unicompartmental osteoarthritis.

The femoral component and tibial tray are intended for cementless or cemented fixation. The porous surfaces of both the femoral and tibial tray components provide biological fixation when used in a cementless application. When the tibial tray is implanted without the use of bone cement, the tibial anchor should be used. When the tibial tray is implanted with bone cement, the tibial anchor should not be used.

Indications for Use Comparison

The purpose of this Traditional 510(k) submission is to seek FDA clearance of the existing devices ENGAGE™ Partial Knee System and JOURNEY II Unicompartmental Knee System components to be used in various combinations to create a hybrid unicompartmental knee system.

Indications for use are the same, no new or modified knee implant components or new device-specific instruments are being introduced as a result of this filing where, ENGAGE™ Partial Knee System used with JOURNEY II Unicompartmental Knee System, are both FDA 510(k) cleared as follows: K190439 (S.E. 11/21/2019) - ENGAGE™ Partial Knee System; K191211 (S.E. 07/25/2019) and K190085 (S.E. 02/11/2019) - JOURNEY II Unicompartmental Knee System.

Together with the existing Smith+Nephew knee implants, these devices will be marketed under the trade name JOURNEY II UK™ and ENGAGE™ Cementless Partial Knee System. Only the use of the respective unicompartmental knee femoral/tibial devices in a hybrid device combination is changing. As a result of the acquisition of ENGAGE Surgical, ENGAGE product line in the US. Smith+Nephew now has responsibility for the ENGAGE™ Partial Knee System and has been listed as the specification developer and the complaint file establishment. The JOURNEY II UK™ and ENGAGE™ Cementless Partial Knee System is an implant system intended for unicompartmental knee arthroplasty. The subject device is a unicondylar femoral and tibial implant set in a hybrid system that incorporates JOURNEY II Unicompartmental Knee System with ENGAGE components, where the JOURNEY II Unicompartmental Knee System components are cemented and the ENGAGE components are cementless. To better fit the patient, the system consists of various sizes for the femoral and tibial components.

Technology Characteristics

The devices that comprise the JOURNEY II UK™ and ENGAGE™ Cementless Partial Knee System are existing devices previously cleared by the FDA. As result, much of the testing makes references to existing information previously provided to the agency. Additional mechanical testing (Contact Area Analysis) was conducted on the subject device to support the use of the components in combination. Based on the testing, there are no new issues related to the safety and effectiveness of the subject device. Clinical data was not needed to support the safety and effectiveness of the subject device.

Non-Clinical and/or Clinical Tests Summary & Conclusion

Substantial Equivalence Information

The JOURNEY II UK™ and ENGAGE™ Cementless Partial Knee System is identical in function, design features, intended use, indications for use, operational principles, because the components are the identical product devices cleared in previous premarket notifications listed in the attachment “Comprehensive Device Description and Principles of Operation Documentation” (See Attachment “02-DEVICE PRESCRIPTION -SE Predicates – CONFIDENTIAL” for Substantial Equivalent Predicates to the JOURNEY II UK™ and ENGAGE™ Cementless Partial Knee System).

Conclusion

No new or modified unicompartmental knee implant components or device specific instruments are being introduced as a result of this filling. The subject device is comprised

of identical product components from previous premarket notifications, the subject device is substantially equivalent to the listed predicates.