October 30, 2024

Smith & Nephew, Inc.
Anne Remington
Regulatory Affairs Specialist II
1450 Brooks Rd
Memphis, Tennessee 38116

Re: K242711
Trade/Device Name: JOURNEY II Unicompartmental Knee System (JOURNEY II UK)
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee Joint Femorotibial Metal/Polymer Non-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSX, KRR, NPJ
Dated: September 9, 2024
Received: September 9, 2024

Dear Anne Remington:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lixin Liu -S

Lixin Liu, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242711

Device Name

JOURNEY II Unicompartmental Knee System (JOURNEY II UK)

Indications for Use *(Describe)*

Unicompartmental knee implants are indicated for restoring either compartment of a knee that has been affected by the following:
• Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis; and
• Partial revisions to replace the tibial insert of the previously implanted JOURNEY II UK knee in the case the femoral and tibial components are well-fixed.

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

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.

510(k) Summary

Prepared on: 2024-10-29

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Smith & Nephew, Inc.
Applicant Address	1450 Brooks Rd Memphis TN 38116 United States
Applicant Contact Telephone	+1.704.397.9060
Applicant Contact	Mrs. Anne Remington
Applicant Contact Email	Anne.Remington@smith-nephew.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	JOURNEY II Unicompartmental Knee System (JOURNEY II UK)
Common Name	JOURNEY II UK Knee System
Classification Name	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulation Number	888.3520
Product Code(s)	HSX, KRR, NPJ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K190085	JOURNEY II Unicompartmental Knee System (JOURNEY II UK)	HSX, KRR, NP
K230653	JOURNEY II UK Knee System	HSX

Device Description Summary

21 CFR 807.92(a)(4)

The purpose of this Traditional 510(k) is to notify the FDA of Smith & Nephew's intent to request clearance for labeling updates, which include indication updates in the IFU/Package Insert, to Smith & Nephew's JOURNEY II Unicompartmental Knee System. There is no significant change in design, technological characteristics, function, sterilization or packaging of the devices as a result of this submission.

The JOURNEY II Unicompartmental Knee System includes femoral components, tibial baseplates, and tibial inserts that restore either compartment of the knee (K190085, K230653). JOURNEY II UK provides joint replacement on a single condylar compartment, meaning that only one condyle will be replaced instead of the entire femoral joint. The femoral component replaces the damaged condylar component of the femur. The tibial baseplate replaced the damaged part of the tibia. The tibial insert is the articulating surface which allows the knee to bend and flex smoothly and is placed above the tibial baseplate.

The subject Smith & Nephew JOURNEY II Unicompartmental Knee System devices are identical in function, design features, materials, sterilization, packaging, manufacturing methods and operational principles to what was previously 510(k) cleared (K190085, K230653). These labeling updates do not affect the safety and effectiveness of the subject devices when used as labeled.

The JOURNEY II Unicompartmental Knee System is intended for unicompartmental knee arthroplasty in skeletally mature patients. The JOURNEY II UK implants are intended for implantation with bone cement.

The Smith & Nephew JOURNEY II Unicompartmental Knee System consists of OXINIUM femoral components, titanium tibial baseplates,

and cross-linked polyethylene (XLPE) tibial inserts. These materials are identical to the material that has been previously cleared in K230653 and K190085.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Unicompartmental knee implants are indicated for restoring either compartment of a knee that has been affected by the following:
• Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis; and
• Partial revisions to replace the tibial insert of the previously implanted JOURNEY II UK knee in the case the femoral and tibial components are well-fixed.

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

Indications for Use Comparison

21 CFR 807.92(a)(5)

The purpose of this Traditional 510(k) is to notify the FDA of our intent to request clearance for changes to Smith & Nephew's JOURNEY II Unicompartmental Knee System labeling, including updated indications.

Indications were updated from the Instructions for Use (K190085, K230653) to meet EU MDR requirements. Indications that could be implied within another cleared indication were removed to consolidate indications for use. The revision indication verbiage was modified to specify only isolated polyethylene insert exchanges (poly swap), in the case the femoral and tibial components are well-fixed, based on clinical evaluation requirements under EU MDR. The updates to the indications do not change the general purpose or disease or condition that the subject devices are intended to be used for; therefore, the updates to the indications do not constitute a new intended use.

The Smith & Nephew JOURNEY II Unicompartmental Knee System is identical in function, design features, materials, sterilization, packaging, manufacturing methods and operational principles to the commercially available predicate device Smith & Nephew JOURNEY II Unicompartmental Knee System (K190085, K230653).

Technological Comparison

21 CFR 807.92(a)(6)

The overall technological characteristic including device design and material of the subject devices are identical to the predicates cleared under the premarket notifications Smith & Nephew JOURNEY II Unicompartmental Knee System (K190085, K230653). As a result, all relevant testing makes references to existing information previously provided to the agency.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The purpose of this traditional 510(k) is to request clearance from FDA for labeling changes to the subject Smith & Nephew JOURNEY II Unicompartmental Knee System implants.

The subject Smith & Nephew JOURNEY II Unicompartmental Knee System devices are identical in function, design features, materials, packaging, sterilization, manufacturing methods and operational principles to what was previously 510(k) cleared (K190085, K230653). These labeling updates do not affect the safety and effectiveness of the subject devices when used as labeled.

Therefore, since there are no changes to the design features, materials, or manufacturing methods of the subject JOURNEY II Unicompartmental Knee System devices, no performance testing (bench, animal, clinical) was required.

Not Applicable.

No modifications are being introduced to the subject devices as a result of this filing. The subject devices are substantially equivalent to the previously 510(k) cleared predicate devices (K190085, K230653).