April 2, 2025

Smith & Nephew, Inc.
Dana Hartlein
Senior Regulatory Affairs Specialist
7135 Goodlett Farms Pkwy
Cordova, Tennessee 38016

Re: K250677
Trade/Device Name: LEGION Total Knee System
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: March 6, 2025
Received: March 6, 2025

Dear Dana Hartlein:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250677

Please provide the device trade name(s).

LEGION Total Knee System

Please provide your Indications for Use below.

• Rheumatoid arthritis;
• Post-traumatic arthritis, osteoarthritis, or degenerative arthritis;
• Posterior stabilized and constrained knee systems are also indicated for the treatment of 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.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K250677

510(k) Summary

Prepared on: 2025-04-01

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Smith & Nephew, Inc.
Applicant Address	7135 Goodlett Farms Pkwy Cordova TN 38016 United States
Applicant Contact Telephone	484-557-4768
Applicant Contact	Ms. Dana Hartlein
Applicant Contact Email	dana.hartlein@smith-nephew.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	LEGION Total Knee System
Common Name	Total Knee Prosthesis
Classification Name	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulation Number	888.3560
Product Code(s)	JWH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K200407	LEGION CR High Flex Insert with JRNY Lock	JWH
K200407	LEGION Deep Dish Insert with JRNY Lock	JWH
K211671	JOURNEY II Medial Dished XLPE Articular Insert	JWH
K220896	Legion Inserts with JRNY Lock	JWH

Device Description Summary

21 CFR 807.92(a)(4)

The purpose of this Special 510(k) is to notify FDA of our intent to market the Smith & Nephew LEGION Medial Stabilized Insert with JOURNEY Lock as part of the LEGION Total Knee System. The subject insert is a line addition to the LEGION Inserts with JOURNEY Lock (K200407) and has undergone design modifications to provide a new articulating surface that incorporates a flatter lateral plateau and extended medial geometry to match the asymmetry of the tibial baseplate, while maintaining the JOURNEY locking mechanism. The subject LEGION Medial Stabilized Inserts with JOURNEY Lock have a size range of 1-2, 3-4, 5-6, and 7-8mm with thicknesses of 9, 10, 11, 12, 13, 15, 18mm, and come in both left (LT) and right (RT) configurations. The LEGION Medial Stabilized XLPE Inserts with JOURNEY Lock are provided sterile via Ethylene Oxide sterilization and are intended for single use only. The subject inserts are intended to be used with compatible knee systems for total knee arthroplasty in skeletally mature patients with or without bone cement.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

- Rheumatoid arthritis;
- Post-traumatic arthritis, osteoarthritis, or degenerative arthritis;
- Posterior stabilized and constrained knee systems are also indicated for the treatment of 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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject LEGION Total Knee System has similar indications for use and the same intended use as the predicates.

Technological Comparison 21 CFR 807.92(a)(6)

The overall function, intended use, material composition, manufacturing processes, and packaging for the LEGION Medial Stabilized Insert with JOURNEY Lock is identical to the commercially available predicate devices identified above (K200407). The new LEGION Medial Stabilized Insert with JOURNEY Lock introduces a new articulating surface compared to the primary predicate LEGION CR High Flex Insert with JRNY Lock. The new articulating surface is similar to that of the secondary predicate, the JOURNEY II Medial Dished XLPE Articular Insert (K211671).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following bench testing was performed for the LEGION Medial Stabilized Insert with JOURNEY Lock:

Tibiofemoral Constraint Testing per ASTM F1223-20, and ISO 21536.
Tibiofemoral Contact Area Testing per ISO 21536.

No clinical testing was performed to support safety and effectiveness of the subject device.

The results of the constraint and contact area testing demonstrated acceptable outcomes. The results demonstrate that the LEGION Medial Stabilized Insert with JOURNEY Lock is substantially equivalent to the currently marketed predicate.