March 13, 2020

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

Re: K200407
Trade/Device Name: LEGION Inserts with JRNY Lock
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, MBH
Dated: February 17, 2020
Received: February 19, 2020

Dear Konrad Wolfmeyer:

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
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200407

Device Name
LEGION Inserts with JRNY Lock

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.

The Smith & Nephew Legion Inserts with JRNY Lock 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.

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

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	March 11, 2020
Contact Person and Address:	Konrad Wolfmeyer Regulatory Affairs Specialist Phone: (901) 399-1367
Name of Device:	LEGION Inserts with JRNY Lock
Common Name:	Tibial Articular Insert Components
Device Classification Name and Reference:	21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis 21 CFR 888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	JWH, MBH
Predicate Device:	Primary Predicate – K071071 – Crosslinked Polyethylene Articular Inserts Predicate – K121443 – JOURNEY II CR Knee System Predicate – K111711 – JOURNEY II BCS Knee System

Device Description

The subject of this Special 510(k) is the LEGION Inserts with JRNY Lock (LEGION Inserts). The subject LEGION Inserts are tibia insert components, and a line extension of the LEGION CR High Flex and Deep Dish inserts cleared under premarket notification K071071. The subject devices were modified by incorporating the identical JOURNEY II locking mechanism from the JOURNEY II CR and JOURNEY II BCS inserts, cleared under premarket notifications K121443 and K111711 respectively.

The subject LEGION Inserts have a size range of 1-2, 3-4, 5-6, 7-8mm with thicknesses of 9, 10, 11, 12, 13, 15, 18, 21mm, and come in cruciate-retaining high flexion (CR HF) and Deep Dish varieties. The LEGION Inserts are manufactured from 7.5MRad Cross-linked Polyethylene

(XLPE) conforming to ASTM F648 and ISO 5834-2, as the predicate LEGION CR Inserts cleared under a premarket notification K071071.

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.

The Smith & Nephew LEGION Inserts with JRNY Lock are single use devices.

Technological Characteristics

A review of the technological characteristics indicates that the LEGION Inserts with JRNY Lock are equivalent to existing, legally marketed predicate devices with regards to mechanical performance and that there are no new issues 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.

A review of this testing has demonstrated that there are no new issues 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 identical in function, intended use, indications for use, and material composition, and very similar in overall design to the predicate devices listed in the following table.

Table 5.1: Substantially Equivalent Predicates

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Crosslinked Polyethylene Articular Inserts (LEGION)	K071071	9/19/2007
Smith & Nephew, Inc.	JOURNEY II CR Knee System	K121443	8/13/2012
Smith & Nephew, Inc.	JOURNEY II BCS Knee System	K111711	9/16/2011

Performance Testing:

To further support a determination of substantial equivalence, leveraged non-clinical bench (mechanical) testing was utilized. A review of the leveraged mechanical data indicates that the subject LEGION Inserts are substantially equivalent to one or more of the previously cleared predicate devices listed in Table 5.1 above. The following performance testing were used as a basis for the determination of substantial equivalence.

- Range of Motion and Constraint

- Tibiofemoral Contact Area Analysis
- Component Interlock Strength Testing

Bacterial endotoxin testing was completed 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.

Conclusion

As previously noted, this Special 510(k) Premarket Notification is being submitted to request clearance for the LEGION Inserts with JRNY Lock. Based on the similarities to the predicate devices, the devices are substantially equivalent to the commercially available predicate devices listed above.