March 25, 2021

Smith & Nephew, Inc.
Michelle Huettner
Director, Regulatory Affairs
1450 Brooks Road
Memphis, Tennessee 38116

Re: K210566
Trade/Device Name: LEGION Porous CR Narrow Femoral Components
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH
Dated: February 22, 2021
Received: February 26, 2021

Dear Michelle Huettner:

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
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)*
K210566

Device Name
LEGION Porous CR Narrow Femoral Components

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. LEGION Porous CR Narrow Femoral Components are indicated for use without bone cement and 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.

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Submitted by:	Smith & Nephew, Inc. Orthopaedics Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	March 18, 2021
Contact Person and Address:	Michelle Huettner Director, Regulatory Affairs Phone: 765-426-6070 Michelle.Huettner@smith-nephew.com
Name of Device:	LEGION Porous CR Narrow Femoral Components
Common Name:	Orthopedic Devices
Device Classification Name and Reference:	21 CFR 888.3565: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	MBH
Predicate Device:	Primary Predicate – K073325 - LEGION Porous Primary Femoral Components Reference Device – K091543 - LEGION Porous Plus HA Primary Femoral Components Reference Device (Narrow) – K112941 - LEGION Narrow Oxinium CR and PS Femoral Components and Device Specific Instruments

Device Description

The subject devices of this premarket notification are the LEGION Porous CR Narrow Femoral Components, which include catalog item offerings with and without HA Coating. These Femoral Components are indicated for use without bone cement applications. The subject devices are a line extension of the predicate devices listed, which are cleared under 510(k) submission numbers K073325 and K091543, with a modification in their femoral components' outer

dimensions making them Narrow Femoral Components (similar to the cleared reference device: LEGION Narrow Oxinium CR and PS Femoral Components and Device Specific Instruments cleared under K112941). The overall design of the subject device is geometrically identical to the predicate devices LEGION Porous Femoral Components (K073325, K091543) with their outer dimensional changes making them Narrow Femoral Components (Reference device K112941).

Design Changes:

The Narrow versions of the Predicate Femoral Component sizes 3, 4, 5, 6, and 7 will have their Medial/Lateral Width and Anterior/Posterior Dimension reduced making them Narrow versions of the cleared predicate devices. The full list of the catalog item numbers in scope for the subject device is included in the Device Description of the submission.

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. LEGION Porous CR Narrow Femoral Components, with and without HA Coating, are indicated for use without bone cement and are single use devices.

Note, the Indications for Use for the subject devices (LEGION Porous CR Narrow Femoral Components) are the same as the cleared indications for use for the Predicate devices for the LEGION Porous CR Femoral Components, with and without HA Coating (K073325 and K091543 respectively).

Technological Characteristics

A review of the technological characteristics indicates that the LEGION Porous CR Narrow Femoral Components are equivalent to existing, legally marketed predicate devices with regards to mechanical performance and that there are no new issues raised related to the safety and effectiveness of the subject devices from Risk Management Plan.

A review of this design verification testing of the modified Femoral components also demonstrate that the subject devices are equivalent to their cleared predicate devices in their intended use and no new issues/risks raised from these design changes.

Substantial Equivalence

The subject devices are substantially equivalent in function, intended use, indications for use, and material composition, and they are very similar in overall design to the cleared predicate devices.

Table 5.1: Substantially Equivalent Predicates

	Manufacturer	Description	Submission Number	Clearance Date
Primary Predicate	Smith & Nephew, Inc.	LEGION Porous Primary Femoral Component	K073325	12/20/2007
Reference Device	Smith & Nephew, Inc.	LEGION Porous Plus HA Primary Femoral Component	K091543	12/21/2009
Reference Device	Smith & Nephew, Inc.	LEGION Narrow Oxinium CR and PS Femoral Components and Device Specific Instruments (Narrow)	K112941	12/20/2011

Performance Testing:

To further support a determination of substantial equivalence, various types of bench testing were conducted or leveraged for the subject, implantable devices in comparison against one or more of the previously cleared predicate devices. The specific types of bench testing included:

- Tibiofemoral constraint analysis testing
- Tibiofemoral contact area analysis testing
- Patellofemoral resistance to lateral subluxation testing

There was no necessary animal pre-clinical testing or clinical testing in scope for the subject devices. In conclusion, the bench performance testing met the predefined acceptance criteria and the results demonstrated substantial equivalence to the cleared predicate.

Conclusion

As previously noted, this Special 510(k) Premarket Notification is being submitted to request clearance for the LEGION Porous CR Narrow Femoral Components, which include catalog item offerings with and without HA Coating. Based on the similarities to the predicate devices, the subject devices are line extensions and substantially equivalent to the commercially available cleared predicate devices listed above.