May 24, 2021

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

Re: K211246
Trade/Device Name: LEGION CR Porous Plus HA 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: April 23, 2021
Received: April 26, 2021

Dear Leah Hawkins:

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., R.A.C.
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)*
K211246

Device Name
LEGION CR Porous Plus HA 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.

The Smith & Nephew Legion CR Porous Plus HA 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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510(k) SUMMARY
Smith & Nephew – LEGION CR Porous Plus HA Femoral Components

510(k)Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Submission:	April 23, 2021
Contact Person:	Leah Hawkins, Regulatory Affairs Specialist T (901) 800-3355 M (901) 463-8447 Additional Contact: Michelle Huettner, Director of Regulatory Affairs T (901) 800-3241 M (765) 426-6070
Name of Device:	LEGION CR Porous Plus HA Femoral Components
Common Name:	Femoral Knee Prosthesis
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 - Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Porous, Coated, Polymer/Metal/Polymer
Predicate Device:	LEGION Porous Plus HA Primary Femoral Components – K091543 (S.E. 12/21/2009)

510(k) SUMMARY
Smith & Nephew – LEGION CR Porous Plus HA Femoral Components

Device Description

The subject of this Special 510(k) is to seek clearance for an additional hydroxyapatite (HA) coating supplier for Smith & Nephew's LEGION CR Porous Plus HA Femoral Components. The LEGION Porous Plus HA Primary Femoral Components were previously cleared for market via premarket notification K091543 (S.E. 12/21/2009). The subject device is used in total knee arthroplasty procedures and is available in sizes 2-8 in both left and right configurations. Like the predicate LEGION Porous Plus HA Primary Femoral Components, the subject device is manufactured from cast cobalt-chrome-molybdenum alloy (ASTM F75) with a cobalt-chrome-molybdenum (ASTM F75) sintered bead porous coating (ROUGHCOAT). Additionally, the LEGION CR Porous Plus HA Femoral Components are coated with a thin layer of plasma-sprayed hydroxyapatite (HA). There has been no change in femoral size, substrate material, porous coating, or device design as a result of this submission.

The only modification of the previously cleared LEGION CR Porous Plus HA Femoral Components is the addition of an alternate supplier to administer the HA coating process. The device design, principle of operation, substrate material, dimensional characteristics, and indications for use for the subject device will not change as a result of the implementation of an alternate HA coating supplier.

Indications 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.

The Smith & Nephew Legion CR Porous Plus HA Femoral components are indicated for use without bone cement and are single use devices.

Technological Characteristics

The HA coating process from the previous supplier to the subject alternate supplier remains unchanged and the new HA coating characteristics meet or exceed the applicable FDA Guidance and ISO Standards. Device comparisons and non-clinical testing show that the subject device LEGION CR Porous Plus HA Femoral Components are substantially equivalent

510(k) SUMMARY
Smith & Nephew – LEGION CR Porous Plus HA Femoral Components

to the predicate LEGION Porous Plus HA Primary Femoral Components (K091543) in terms of intended use, indications for use, design, materials, performance characteristics, and operational principles.

Substantial Equivalence Information

The Smith & Nephew LEGION CR Porous Plus HA Femoral Components are identical in function, design features, intended use, indications for use, operational principles, manufacturing processes, and similar in materials as the commercially available predicate devices listed below in **Table 6.1**.

Table 6.1: Predicate Device

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	LEGION Porous Plus HA Primary Femoral Component	K091543	12/21/2009

Performance Testing

Smith & Nephew conducted non-clinical fatigue testing of the dual-layer coating (ROUGHCOAT and HA) with the HA coating applied by the subject alternate supplier. The results of this testing demonstrated that the coating properties, via subject alternate supplier, perform equivalent to the predicate LEGION Porous Plus HA Primary Femoral Components (K091543).

Fatigue testing and coating characterization was completed in line with FDA's guidance document entitled, "*510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants*," dated March 10, 1995 (revised 2/20/1997). A review of this testing has demonstrated that there are no new risks related to the safety and effectiveness of the subject device with HA coating process performed by the subject alternate HA coating supplier. Precise HA coating characterizations (static shear, shear fatigue, and HA powder values) are discussed in detail in the supplier's Master File.

510(k) SUMMARY
Smith & Nephew – LEGION CR Porous Plus HA Femoral Components

Based on the testing within this premarket notification, 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.

Conclusion

As previously noted, this Special 510(k) Premarket Notification is to seek clearance of the addition of alternate hydroxyapatite (HA) coating supplier for the LEGION CR Porous Plus HA Femoral Components. Based on the similarities to the predicate device and HA coating testing justifications, there are no new risks related to the safety and effectiveness and the subject device is substantially equivalent to the commercially available cleared predicate device.