



Smith & Nephew, Inc.
Michael Scott
Senior Regulatory Affairs Specialist
1450 Brooks Rd.
Memphis, Tennessee 38116

March 5, 2018

Re: K180334

Trade/Device Name: LEGION 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: February 5, 2018

Received: February 6, 2018

Dear Michael Scott:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K180334

Device Name

LEGION Knee System

Indications for Use (Describe)

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. 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.
5. 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.
6. Hinge 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 absent or incompetent.

The LEGION Knee System - Finned Tibial Wedges are for single use only and are intended for implantation 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.

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
PRASStaff@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."

510(k) Summary
Smith & Nephew LEGION Knee System

SUBMITTER:
I.

Smith & Nephew, Inc.
Orthopaedic Division
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Phone: (901) 396-1633
Fax: (901) 566-7159

Contact Person: Michael Scott
Date Prepared: February 23, 2018

II. DEVICE

Name of Device: LEGION Knee System
Common Name: Knee Prosthesis
Regulatory Class: 2

Classification Name, Regulation Number, Product Codes, Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3560) JWH Prosthesis, knee, patello/femorotibial, semi-constrained, uncemented, porous, coated, polymer/metal/polymer (21 CFR888.3565)

PREDICATE DEVICE Primary Predicate: LEGION Revision Hemi-Stepped Tibia Augment (K043440 (S.E. 02/18/2005))
Predicate 2: LEGION Cones (K162775 (S.E. 01/13/2017))

Reference Predicate 1: Legion Hinge Tibia Tray (K081111 (S.E. 07/23/2008))

The predicate devices have not been subject to a design related recall.

III. Device Description

Smith & Nephew has also developed the subject LEGION Knee System - Finned Tibial Wedges for tibial bone deficiency. The tibia augments (wedges) are line additions to the augments currently included as part of the Legion Revision and Legion Hinge Knee Systems. The LEGION Finned Tibial Wedges are asymmetrically shaped to match the perimeter profile of Legion Revision and Legion Hinge tibia bases. The Legion Finned Tibia Wedges will be offered in sizes 2-8, in left and right hand configurations, with 10mm, 15mm, and 20mm height increments. The subject wedges will consist of grit blasted tibia augments that are intended to address defects in the proximal tibia.

The subject LEGION Finned Tibial Wedges are full wedges with a similar general design and fundamental scientific technology to the existing predicate LEGION Revision Hemi-Stepped Tibia Augments (K043440 (S.E. 02/18/2005)) in the Smith & Nephew LEGION Knee System Portfolio. The subject LEGION Finned Tibial Wedges mate with the LEGION Tibial Baseplates via screws and interface with host bone to replace tibial bone loss in complex knee surgeries. The top and bottom surface of the LEGION Finned Tibial Wedges will have a grit-blasted surface for cement adhesion. The LEGION Finned Tibial Wedges are an extension of the LEGION portfolio of wedges consisting of a modified small fin to the underside of a full wedge. The subject LEGION Finned Tibial Wedges replicate the fins on the tibial baseplate that are covered when a standard Smith & Nephew full tibial wedge is used. The small fins on the tibial baseplate and on the subject LEGION Finned Tibial Wedges are designed to provide additional rotational stability of the final tibial implant construct.

The subject LEGION Finned Tibial Wedge consists of a Ti-6Al-4V alloy wedge with a grit-blasted surface identical to that of Smith & Nephew's current LEGION Revision Hemi-Stepped Tibia Augment (K043440 (S.E. 02/18/2005)). The use of a wedge is intended to add thickness to the total knee construct when the surgeon determines the need for additional construct height. The subject LEGION Finned Tibial Wedges is designed to interface with Smith & Nephew LEGION Tibial Trays and host bone along with bone cement.

The purpose of this 510(k) submission is to add additional tibial wedge components to the Smith & Nephew Legion Knee System of implants.

IV. INDICATIONS FOR USE

- 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.
- 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.
- Hinge 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 absent or incompetent.

The LEGION Finned Tibial Wedges are for single use only and are intended for implantation with bone cement.

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject LEGION Finned Tibial Wedges have identical indications for use, and a similar intended use to the predicate LEGION Revision Hemi-Stepped Tibia Augment Implants (S.E. (K043440 (S.E. 02/18/2005))). The primary difference between the subject device and the predicate device is that the subject wedges are a full wedge with various thicknesses as opposed to hemi-wedges that are 5mm thick. Additionally the subject LEGION Finned Tibial Wedges contain a modified small fin to the underside of a full wedge. The addition of the small fins on the LEGION Finned Tibial Wedges are intended to provide additional

rotational stability of the final tibial implant construct. Finally, this submission has included additional thicknesses of wedges (10mm, 15mm and 20mm). As part of the design control activities the additional thickness wedges have been shown to not create any new risks compared to the predicate devices.

The subject LEGION Finned Tibial Wedges are manufactured from identical Ti-6Al-4V alloy material and follow an identical gamma sterilization method as the predicate LEGION Revision Hemi-Stepped Tibia Augment implants (S.E. (K043440 (S.E. 02/18/2005)). Both the subject LEGION Finned Tibial Wedges and predicate LEGION Revision Hemi-Stepped Tibia Augment implants are intended to be used with Smith and Nephew Knee constructs including: stems, set screws, offset couplers, femoral cones, distal femoral wedges, distal femoral wedge screws, femoral hinge assembly, post bolts, post sleeves, hinge inserts, hinge insert lock screws, hinge tibial trays, tibial hemi wedges, tibial wedge screws, tibial cones, set screws, and patellas.

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.

Therefore, the technological characteristics of the subject device are the similar to the technological characteristics of the predicate device LEGION Revision Hemi-Stepped Tibia Augment implants (S.E. (K043440 (S.E. 02/18/2005)).

VI. PERFORMANCE DATA

The following performance data are provided in support of the substantial equivalence determination.

Biocompatibility

The biocompatibility evaluation for the LEGION Finned Tibial Wedge was conducted in accordance with FDA’s Draft Guidance for Industry and FDA Staff “Use of International

Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process”.

The subject LEGION Finned Tibial Wedge are permanent implants and will be classified as permanent, >30 day body contact according to ISO-10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process”.

The subject LEGION Finned Tibial Wedge are manufactured from identical Ti-6Al-4V alloy materials as the LEGION Revision Hemi-Stepped Tibia Augment implants (S.E. (K043440 (S.E. 02/18/2005)) predicate device, in accordance with the following ASTM standard: 1472-Standard Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400). Biocompatibility evaluation has been completed and a summary rationale has been provided for the subject LEGION Finned Tibial Wedges.

Mechanical testing

To further support a determination of substantial equivalence, a Finite Element Analysis and engineering rationale were conducted on the proposed LEGION Finned Tibial Wedges. Results demonstrated that the proposed devices are substantially equivalent to the predicate LEGION Revision Hemi-Stepped Tibia Augment implants and LEGION Cones System.

The subject devices with pre-determined acceptance criteria met the acceptance criteria for all outputs.

VII. CONCLUSIONS

Based on the verification evidence activities provided in the pre-market notification, the subject LEGION Finned Tibial Wedges are substantially equivalent to the legally marketed predicate devices: LEGION Revision Hemi-Stepped Tibia Augment implants (S.E. (K043440 (S.E. 02/18/2005)) and Predicate 2: LEGION Cones (K162775 (S.E. 01/13/2017)).