DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 13, 2017

Smith & Nephew, Inc.
Ms. Dongeun Kim
Regulatory Affairs Specialist I
1450 Brooks Road
Memphis, Tennessee 38116

Re: K162775
Trade/Device Name: Legion Cone 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, MBH
Dated: September 7, 2016
Received: October 3, 2016

Dear Ms. Dongeun Kim:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
~~XBX~~ K162775

Device Name
Smith & Nephew Legion Cone System

Indications for Use *(Describe)*
The Legion Cones are intended to be used with the Legion Revision and Legion Hinge knee systems. The Legion Cones are indicated for the following:

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 of incompetent.

These are single use implants and are intended for use with and without 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.

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We are smith&nephew

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	September 30, 2016
Contact Person and Address:	Ms. Dongeun Kim Regulatory Affairs Specialist I T 901-399-1151 F 901-566-7120
Name of Device:	Smith & Nephew, Inc. Legion Cone System
Common Name:	Knee Prosthesis
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

Device Description

Subject of this Traditional premarket notification is the Smith & Nephew Legion™ Cone System. The Smith & Nephew Legion Cone System consists of porous coated tibial and femoral augments to address cavitary defects in the proximal tibia or distal femur. The system will also include the necessary instrumentation for the surgeon to prepare the tibia and femur for implantation of the augments.

The components of the Smith & Nephew Legion Cone System are as follows:

- Titanium alloy (Ti-6Al-4V) tibial cones of 2 heights and 7 sizes
- Titanium alloy (Ti-6Al-4V) hand-specific femoral cones of 1 height and 7 sizes

The Legion Tibial and Femoral Cones are a one piece, conically shaped device with cannulation all the way through the cone which allows fixation to the Legion Revision and Legion Hinge tibial baseplates, femoral components, offset couplers, augments/wedges, and stem constructs.

The Legion Tibial and Femoral Cones are similar to the primary predicate Zimmer Trabecular™ Metal Tibial and Femoral Cone Augments cleared via premarket notification K053340. The Legion Tibial Cones will be available in heights of 25mm (short) and 40mm (long) and inner diameters (ID) of 18mm-30mm, in 2mm increments. The Legion Femoral Cones will be available in a height of approximately 35mm and inner diameters of 18mm-30mm, in 2mm increments. The Legion Femoral Cones will be provided in left and right orientations. The subject tibial and femoral cones are manufactured from forged titanium alloy (Ti-6Al-4V) that conforms to ASTM F 1472. The subject tibial and femoral cones also have an external

asymmetric (Stiktite™) porous coating specification identical to the porous coating of the reference predicate Smith & Nephew SMF™ Hip Stems cleared via premarket notifications K080625, K103256, and K123012. The interior side of the subject cones has a grit-blasted surface specification for cement adhesion identical to the grit-blasted surface of reference predicate Smith & Nephew Genesis II Total Knee System cement-on-augment devices cleared via premarket notification K951987.

Intended Use
The Legion Cones are intended to be used with the Legion Revision and Legion Hinge knee systems. The Legion Cones are indicated for the following:

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.

These are single use implants and are intended for use with and without bone cement.

Technological Characteristics
Smith & Nephew has conducted a mechanical evaluation of the subject Legion Tibial and Femoral Cone Augments of the following:

- Fatigue Strength
- Push-Out Strength
- Torsional Shear
- Tensile Attachment Strength

A review of testing has demonstrated that there are no new issues related to the safety or effectiveness of the subject devices. Clinical data was not needed to support the safety and effectiveness of the subject devices.

Substantial Equivalence Information
The intended use, indications for use and technological characteristics of the subject Smith & Nephew Legion Tibial and Femoral Cones are substantially equivalent to the predicate devices listed in Table 5.1 below.

Table 5.1: Predicate Comparison Matrix – Legion Tibial and Femoral Cones

Design Aspect Reviewed	Legion Tibial and Femoral Cones (Subject Devices)	Zimmer Trabecular Metal™ Tibial and Femoral Cone Augments (Primary Predicate)	SMF Hip Stems with Stiktite (Stiktite Reference Predicate)	Genesis II Hemi Stepped Augment (Grit-Blast Reference Predicate)
510(k) Number	None, Subject Devices	K053340	K080625, K103256, K123012	K951987
Manufacturer	Smith & Nephew, Inc.	Zimmer	Smith & Nephew, Inc.	Smith & Nephew, Inc.
Similar Indications for Use	Yes	Yes	Yes	Yes
Size Offering	Femoral Cones: 18mm, 20mm, 22mm, 24mm, 26mm, 28mm, 30mm (inner diameters) in one height Tibial Cones: 18mm, 20mm, 22mm, 24mm, 26mm, 28mm, 30mm (inner diameters) in Short and Long	Femoral Cones: 30mm, 40mm, 50mm; Small, Medium, and Large; M/L or A/P Tibial Cones: Full and Stepped (15mm/30mm, 30mm/15mm); Sizes 48-67	-1, 0, 1, 2, 3, 4, 5, 6, 7, 8, 9	1-2, 3-4, 5-6, 7-8 Thickness: 10mm and 15mm
Sterilization Method	Gamma	Gamma	Gamma	Gamma
Material	Substrate - Titanium Alloy (ASTM F1472) Porous Coating - C.P. Titanium (ASTM F67)	Trabecular™ Metal	Substrate - Titanium Alloy (ASTM F1472) Porous Coating - C.P. Titanium (ASTM F67)	Ti 6Al 4V (ASTM F1472)
Grit-Blast Surface Exists	Yes	No	Yes	Yes
Cemented or Cementless	Cemented and Cementless	Cemented and Cementless	Cementless	Cemented

Conclusion

This Traditional 510(k) Premarket Notification is being submitted to request clearance for the Smith & Nephew Legion Cone System. Based on the similarities to the predicate devices and a review of the mechanical testing performed, the subject devices are substantially equivalent to the above predicate devices.