November 16, 2017

Smith & Nephew, Inc.
Shereen Bienz
Senior Regulatory Affairs Specialist
1450 E. Brooks Road
Memphis, Tennessee 38116

Re: K173331
Trade/Device Name: JOURNEY II XR Knee Instruments
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: October 20, 2017
Received: October 23, 2017

Dear Shereen Bienz:

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

Indications for Use

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

510(k) Number *(if known)*
K173331

Device Name
Journey II XR Knee Instruments

Indications for Use *(Describe)*
Smith & Nephew Journey II XR Instruments are accessory devices intended to be used to assist in the implantation of Smith & Nephew Journey II XR Knee System and their cleared 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 Journey II XR Knee system components are indicated for use only with 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. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	November 13, 2017
Contact Person and Address:	Shereen Bienz Senior Regulatory Affairs Specialist T (901) 800-3161 F (901)
Name of Device:	Smith & Nephew, Inc. Journey II XR Knee System Instruments
Common Name:	Knee Prosthesis
Device Classification Name and Reference:	21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	JWH

Device Description

Subject of this Special Premarket Notification are modified Journey II XR Instruments. The subject devices are modifications of existing instrumentation cleared for use with the Journey II XR Knee system.

Technological Characteristics

Biocompatibility assessments for the instruments were conducted per the recommendations of ISO 10993-1 and the FDA guidance document, *Use of International Standard ISO 10993-1, "Biological evaluation of medical device – Part 1: Evaluation and testing within a risk management process,"* issued June 16, 2016. A review of the results indicates that the modified knee instruments are equivalent to existing, legally marketed predicate instrumentation 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.

Intended Use

Journey II XR Instruments are accessory devices and intended to be used to assist in the implantation of Smith & Nephew Journey II XR Knee systems. Table 1 includes the Smith & Nephew Total Knee systems to be used in conjunction with the subject devices.

Table 2: Smith & Nephew Inc. Compatible Total Knee Systems

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Smith & Nephew, Inc. Journey II XR Knee system	K141471	11/14/2014
Smith & Nephew, Inc.	Smith & Nephew, Inc. Journey II XR Knee system	K152726	10/21/2015

Indications for Use

Smith & Nephew Journey II XR Instruments are accessory devices intended to be used to assist in the implantation of Smith & Nephew Journey II XR Knee System and their cleared 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 Journey II XR Knee system components are indicated for use only with cement and are single use devices.

Substantial Equivalence Information

The substantial equivalence of the Journey II XR Instruments is based on its similarities in indications for use, design features, and operational principles to the predicate systems listed in the following table.

Table 1: Predicate Devices

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Smith & Nephew, Inc. Journey II XR Knee system	K141471	11/14/2014
Smith & Nephew, Inc.	Total Knee Instruments	K121393	08/08/2012

Performance and Biocompatibility Testing

The following testing was conducted to evaluate substantial equivalence:

- Biocompatibility risk assessment on the materials was performed in accordance with FDA guidance, Use of International Standard ISO 10993-1, "Biological evaluation of medical device – Part 1: Evaluation and testing within a risk management process," issued June 16, 2016
- Testing was performed to evaluate impact resistance of the proposed tibial impactor design to the previously tested current design
- Testing was performed to evaluate the performance of the modified keel prep instruments as compared to the predicate keel prep instruments

Conclusion

As previously noted, this Special 510(k) Premarket Notification is being submitted to request clearance for modified Journey II XR Instruments. Based on the similarities to the predicate components and a review of the testing performed, the device is substantially equivalent to above predicate systems.