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

October 21, 2015

Smith & Nephew, Incorporated
Brad Sheals
Principal Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K152726
Trade/Device Name: Journey II XR 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: September 18, 2015
Received: September 22, 2015

Dear Mr. Sheals:

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 Parts 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" (21CFR 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 yours,

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)*
K152726

Device Name
Journey II XR Knee System

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 Journey II Total 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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 18, 2015
Contact Person and Address:	Brad Sheals Principal Regulatory Affairs Specialist T 901-399-6897 F 901-566-7911
Name of Device:	Smith & Nephew, Inc. Journey II XR
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

The Journey II XR tibial baseplate and inserts were previously cleared for market via premarket notification K141471. Subject of this premarket notification are minor modifications to the insert locking mechanism on the tibial baseplate and insert.

The Journey II XR components are available in medial and lateral cross-linked polyethylene articular inserts which will be available in left and right hand and titanium alloy (Ti-6Al-4V) tibial bases which will be available in left and right hand

The Journey II XR Knee system will use existing Journey II CR femoral components and existing patella components compatible with the Journey II CR femoral as well as device specific instruments.

Intended Use

Total knee components are indicated for 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. The Journey II Total Knee system components are indicated for use only with cement and are single use devices.

Technological Characteristics
Mechanical testing has been conducted to address the locking mechanism design change. The following verification testing has been conducted:

- Component Interlock Strength of the Tibial Insert Locking Mechanism
- Fatigue Strength Testing Of The Tibial Metal Base Tray, Cement And Polyethylene Insert Construct – Rationale
- Tibial Base Fatigue Testing– FEA

A review of the results indicates that the Journey II XR tibial baseplate and inserts are equivalent to the existing, legally marketed predicate devices 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.

Substantial Equivalence Information
The subject devices are identical in function, intended use, indications for use, and material composition, and very similar in overall design to the Journey II XR knee system cleared via premarket notification K141471. The device subject of this premarket notification is a modification to the aforementioned device**.**

Table 1: Substantially Equivalent Predicates to the Modified Journey II XR components

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Journey II XR Knee System	K141471	11/14/2014

Conclusion
As previously noted, this Special 510(k) Premarket Notification is being submitted to request clearance for the modified Journey II XR tibial baseplate and inserts. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to above predicate knee system.