June 4, 2020

Smith & Nephew, Inc.
Brad Sheals, MS
Senior Regulatory Affairs Specialist
Advanced Surgical Devices Division
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K200227
Trade/Device Name: Journey II XR Knee Instrument
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: May 11, 2020
Received: May 12, 2020

Dear Brad 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. 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,

for Ting Song, Ph.D., R.A.C.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200227

Device Name
JOURNEY II XR Knee Instruments

Indications for Use *(Describe)*
Journey II XR Instruments are accessory devices and intended to be used to assist in the implantation of Smith & Nephew Journey II XR Knee System and their cleared indication 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. Advanced Surgical Devices Division 7135 Goodlett Farms Parkway Cordova, Tennessee 38016
Date of Submission:	June 3, 2020
Contact Person:	Brad Sheals, Regulatory Affairs Manager T (901) 399-6897 F (901) 566-7911
Name of Device:	Journey II XR Knee Instrument
Common Name:	Knee Instrument
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
Predicate Device:	Smith & Nephew, Inc. Journey II XR Knee System Instruments - K173331

Device Description:

The subject of this Traditional 510(k) is a design modification (i.e. tip geometry) to the Journey II XR Tibial Posterior Keel Punch. The Journey II XR Tibial Posterior Keel Punch are reusable instrument and are intended to be used to prepare for the posterior keel of the tibia baseplate implant and act as a guide for the Anterior Keel Punch. The Journey II XR Keel Punch were previously cleared for market via premarket notification K173331.

The Journey II XR Keel Punch are available in same size range as the predicate.

Indication for 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 System and their cleared indication 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 Total Knee system components are indicated for use only with cement and are single use devices.

The above indications are substantially equivalent to the indications cleared for the Smith & Nephew, Inc. Journey II XR Knee System Instruments cleared under K173331. The Smith & Nephew Journey II XR Total Knee systems were cleared under K141471 and K152726.

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Technological Characteristics

Device comparisons described in this premarket notification demonstrate that the subject device Journey II XR Keel Punch are substantially equivalent to the below listed legally marketed predicate devices with regard to intended use, indications for use, design, material and performance characteristics.

Substantial Equivalence Information

As confirmed in the table below, the overall design, indications for use and sterilization for the subject Journey II XR Keel Punch is substantially equivalent to the following commercially available predicate device.

Design Features	Subject Journey II XR Tibial Posterior Keel Punch	Predicate Journey II XR Tibial Posterior Keel Punch
Manufacturer	Smith & Nephew, Inc.	Smith & Nephew, Inc K173331 SE 11/16/2017
Indication for 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 and their cleared indication 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 Total Knee system components are indicated for use only with cement and are single use devices.	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 and their cleared indication 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 Total Knee system components are indicated for use only with cement and are single use devices.
Material	Stainless Steel	Stainless Steel
Coating	Chrome Coat	Chrome Coat
Sizes	Same 1-2, 3-4, 5-6, 7-8	Same 1-2, 3-4, 5-6, 7-8
Sterilization	Non-sterile	Non-sterile

Performance Testing

To further support a determination of substantial equivalence, non-clinical bench (mechanical) testing were conducted on the Journey II XR Keel Punch. A review of the mechanical data and the technical memo, indicates that the Journey II XR Keel Punch are substantially equivalent to predicate devices listed in the Table above.

The following tests were used as a basis for the determination of substantial equivalence.

- Finite Element Analysis
- Stress Distribution Test

A review of the above testing demonstrated that there are no new issues related to the safety and effectiveness of the subject device and will perform as intended.

Conclusion

As previously noted, this 510(k) Premarket Notification is being submitted for a design modification to the Journey II XR Tibial Posterior Keel Punch. Based on the similarities to the predicate devices and a review of the mechanical testing performed, the subject device is substantially equivalent to the commercially available predicate devices listed above.