Smith & Nephew, Inc.
Meenakshi Gupta
Senior Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

July 25, 2019

Re: K191211
Trade/Device Name: JOURNEY II Unicompartmental Knee System
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee Joint Femorotibial Metal/Polymer Non-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSX, KRR, NPJ
Dated: May 3, 2019
Received: May 6, 2019

Dear Meenakshi Gupta:

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 Vesa Vuniqi, MS
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)*

K191211

Device Name

JOURNEY II Unicompartmental Knee System

Indications for Use *(Describe)*

Unicompartmental knee implants are indicated for restoring either compartment of a knee that has been affected by the following:

- Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis.
- Correction of functional deformity.
- Revision of previous arthroplasty procedures.
- Treatment of fractures that are unmanageable using other techniques.

Unicompartmental knee implants are single use only and are intended for implantation only 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.

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510(K) SUMMARY

Submitted by:	Smith & Nephew, Inc. Advanced Surgical Devices Division 7135 Goodlett Farms Parkway Cordova, Tennessee 38016
Date of Submission:	May 3, 2019
Contact Person:	Meenakshi Gupta, Sr. Regulatory Affairs Specialist T (901) 399-6139 F (901) 721-2748
Name of Device:	Smith & Nephew, Inc. JOURNEY II◊ Unicompartmental Knee System (Journey II UK)
Common Name:	Knee Prosthesis
Device Classification Name and Reference:	21 CFR 888.3520 Knee Joint Femorotibial Metal/Polymer Non-Constrained Cemented Prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	HSX, KRR, NPJ
Predicate Device:	Primary Predicate: JOURNEY II◊ Unicompartmental Knee System (Journey II UK)–K190085 Secondary Predicate: Zimmer Unicompartmental Knee System—K160738 The predicate devices have not been subject to a design related recall.

Device Description:

The subject of this traditional 510(k) is to add the MR safety information to the Journey II Unicompartmental Knee System (Journey II UK) labeling. The Journey II UK was cleared under K190085.

Journey II UK system consist of a femoral implant, tibia baseplate, modular articular insert, and requisite US Class II surgical instruments.

The package insert and label of Journey II UK is being updated to add MR conditional information.

The indication for use of Journey II UK system was updated to clarify the definition of the revision cases. This change does not change the indication for use.

Indications for Use

Unicompartmental knee implants are indicated for restoring either compartment of a knee that has been affected by the following:

- Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis.
- Correction of functional deformity.
- Revision of previous arthroplasty procedures.
- Treatment of fractures that are unmanageable using other techniques.

Unicompartmental knee implants are single use only and are intended for implantation only with bone cement.

Technological Characteristics

The device design, material, and indications for use of the subject device are same as the predicate JOURNEY II UK system cleared under K190085.

Performance Data

Below listed Magnetic resonance imaging (MRI) compatibility testing were conducted as per the FDA's guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment", December 11, 2014 and the standards listed below:

1. Magnetically induced displacement force (ASTM F2052)
2. Magnetically induced torque (ASTM F2213)
3. Radiofrequency (RF) induced heating (ASTM F2182)
4. MR image artifact (ASTM F2119)

Substantial Equivalence Information

The device design, materials, and indications for use for the Journey II UK are substantially equivalent to the commercially available predicate devices identified in table below:

Table 6.1: Predicates to the Journey II UK

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Journey II Unicompartmental Knee System	K190085	02/11/2019
Smith & Nephew, Inc.	Zimmer Unicompartmental Knee System (ZUK)	K160738	06/15/2016

Conclusion

In summary, the Smith & Nephew's JOURNEY II Unicompartmental Knee System is identical in function, design features, intended use, indications for use, materials, sterilization, manufacturing methods, and operational principles as the predicate device JOURNEY II Unicompartmental Knee System cleared under K190085