



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

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

October 28, 2015

Re: K152315

Trade/Device Name: Journey II Uni Tibial Base and Insert
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented
prosthesis
Regulatory Class: Class II
Product Code: HSX
Dated: October 1, 2015
Received: October 5, 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

**Premarket Notification
Indications for Use Statement**

510(k) Number (if known): K152315

Device Name: Journey II Uni Tibial Base and Insert

Indications for Use:

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

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and
- 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.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Submitted by: Smith & Nephew, Inc.
Orthopaedic Division
1450 East Brooks Road
Memphis, Tennessee 38116

Date of Summary: [October 15, 2015](#)

Contact Person and Address: Brad Sheals
Principal Regulatory Affairs Specialist
T 901-399-6897
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Name of Device: Smith & Nephew, Inc. Journey II Uni Tibial Baseplate and Insert

Common Name: Knee Prosthesis

Device Classification Name and Reference: 21 CFR 888.3520 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Device Class: Class II

Panel Code: Orthopaedics/87

Product Code: HSX

Device Description

The Journey II Uni tibial baseplate and inserts are modifications of the existing Journey Uni tibial baseplate and inserts that were previously cleared for market via K102069 (baseplates) and K061011 (inserts). The subject of this premarket notification are modifications to the insert locking mechanism on the tibial baseplate and insert, articular surface geometry, sizing of baseplate and inserts, and characteristics of the cemented surface of the baseplate. Additional device specific instruments are also included as part of the submission.

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

The Journey II Uni tibial baseplate and inserts will use existing Journey Uni femoral components cleared via K081351 or GENESIS Uni femoral components cleared via K912735.

Intended Use

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

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and
- 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

Mechanical verification testing/analysis conducted for the subject device includes:

- Unsupported Baseplate Fatigue Testing
- Static testing of the insert locking mechanism including ML/AP Shear Load
- Fully Supported Fatigue/Cement Adhesion Testing
- Contact Area Analysis

A review of the results indicates that the Journey II Uni 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 device(s). Clinical data was not needed to support the safety and effectiveness of the subject device(s).

Substantial Equivalence Information

The subject devices are identical in function, intended use, indications for use, and very similar in overall design to the Journey Uni knee system cleared via premarket notification K102069 and K061011. The device subject of this premarket notification is a modification to the aforementioned device.

Table 1: Substantially Equivalent Predicates to the Journey II Uni Tibial baseplates and inserts

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Journey Uni tibial baseplates	K102069	10/5/2010
Smith & Nephew	Competitor Unicompartmental Tibial Baseplate Components	K061011	07/11/2006
Smith & Nephew, Inc.	Journey II XR Knee System	K141471	11/14/2014
Smith & Nephew, Inc.	GENESIS Unicompartmental Knee System	K912735	12/27/1991

The substantial equivalence of the subject devices are based on its similarities in indications for use, design features, and operational principles to the predicate systems listed in the following table.

Table 2: Comparison to Substantially Equivalent Devices

Design Aspect Reviewed	Journey II Uni	Journey Uni Tibial Base	Journey Uni Insert (Competitor)	Journey II XR (reference predicate)	GENESIS Uni Insert (reference predicate)
510(k) Number	Subject 510(k)	K1020269	K061011	K141471	K912735
Manufacturer	Smith & Nephew, Inc.	Smith & Nephew, Inc.	Smith & Nephew, Inc.	Smith & Nephew, Inc.	Smith & Nephew, Inc.
Similar Indications for Use	Yes- HSX	Yes-HSX	Yes-HSX	No- JWH	Yes- HSX
Similar Sterilization Methods	ETO/Gamma	Yes	Yes	Yes	Yes
Unicondylar Design	Yes	Yes	Yes	No (Total knee)	Yes
Insert material	XLPE	N/A	UHMWPE	XLPE	UHMWPE
Similar Locking Mechanism	Anterior/Posterior snap fit	Yes	Yes	Yes	Medial/Lateral snap fit
Similar Articular Surface Geometry	Non-conforming	N/A	No (flat)	No (Conforming)	Non-conforming
Tibial base material	Ti-6Al-4V	Ti-6Al-4V	N/A	Ti-6Al-4V	N/A
Similar Manufacturing Process	Yes	Yes	Yes	Yes	Yes

Conclusion

As previously noted, this Special 510(k) Premarket Notification is being submitted to request clearance for the Journey II Uni tibial baseplate and inserts, which are modifications of existing Smith & Nephew Unicondylar tibial baseplates and inserts. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to the above predicate knee systems.