510(k) Summary

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FEB 27 2012

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	February 21, 2012
Contact Person and Address:	Shereen Myers, Senior Regulatory Affairs Specialist T (901) 399-6325 F (901) 566-7075
Name of Device:	Smith & Nephew, Inc Journey II Deep Dished Articular Inserts
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 Traditional Premarket Notification are the Journey II Deep Dished articular inserts. The Journey II Deep Dished articular insert is a cruciate stabilizing tibial insert that is intended to be used with the Journey II BCS (K111711) and Journey BCS (K042515) knee systems when the posterior cruciate ligament (PCL) is sacrificed and an insert with a post is not a viable option for the patient. Components of this premarket notification include:

- Cruciate substituting (deep dished) articular inserts which will initially be available in sizes 1-2, 3-4, 5-6, and 7-8 in right and left designs. Journey II Deep Dished inserts will be offered in 9-21 mm thicknesses and manufactured from cross-linked polyethylene (7.5 Mrad XLPE) material and conventional non-cross-linked Ultra-High Molecular Weight Polyethylene (UHMWPE) material.
- Cruciate substituting (deep dished) articular insert trial implants manufactured from Radel.

Technological Characteristics

A review of the mechanical data indicates that the Journey II Deep Dished Articular Insert is capable of withstanding expected *in vivo* loading without failure. The following mechanical testing of the Journey II Deep Dished inserts was performed:

- Tibiofemoral Contact Area Analysis
- Tibiofemoral Constraint Testing

A review of this testing has demonstrated that there are no new issues related to the safety and effectiveness of the subject devices. Due to the similarities to predicate devices, no additional biocompatibility or mechanical testing was required to support 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

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.

Substantial Equivalence Information

The substantial equivalence of the Journey II Deep Dished Articular Inserts 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: Comparison to Substantially Equivalent Devices

Design Aspect Reviewed	Journey II Deep Dished Inserts	Journey II BCS Knee System	High Performance Knee System	VKS Knee System	Profix Conforming Plus Tibial Insert	Profix Flex Cruciate Retaining Articular Insert	Genesis II Total Knee System
510(k) Number	Subject 510(k)	K111711	K042515	K022204	K946236	K051229	K951987
Manufacturer	Smith & Nephew, Inc	Smith & Nephew, Inc	Smith & Nephew, Inc	Plus Orthopaedics	Smith & Nephew, Inc.	Smith & Nephew, Inc.	Smith & Nephew, Inc.
Similar Indications for Use	Subject device	Y	Y	N	Y	Y	Y
Dished Insert (Cruciate Substituting)	Y	N	N	Y	Y	N	Y
Similar Sterilization Method	Subject device	Y	Y	Y	Y	Y	Y
Material	XLPE and UHMWPE	Articular Inserts - XLPE and UHMWPE	Articular Inserts - UHMWPE	Articular Inserts - UHMWPE	Articular Inserts – UHMWPE	Articular Inserts – UHMWPE	Articular Inserts - UHMWPE
Similar Manufacturing Process	Subject device	Y	Y	Y	Y	Y	Y

Conclusion

As previously noted, this Traditional 510(k) Premarket Notification is being submitted to request clearance for the Journey II Deep Dished Articular Inserts. Based on the similarities to the predicate components and a review of the validation testing performed, the device is substantially equivalent to above predicate systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 27 2012

Smith & Nephew, Inc.
% Ms. Shereen Myers
Senior Regulatory Affairs Specialist
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K113482
Trade/Device Name: Journey II Deep Dished Articular Inserts
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: February 21, 2012
Received: February 23, 2012

Dear Ms. Myers:

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.

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.

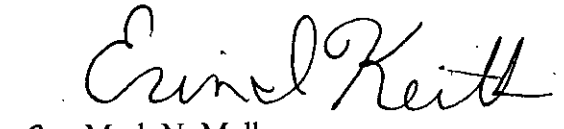
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K113482

Device Name: Journey II Deep Dished Articular Inserts

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. 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.

Prescription Use	X	AND/OR	Over-The-Counter Use	
(Part 21 CFR 801 Subpart D)			(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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113482