K111711 #1/2

We are **smith&nephew**

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	June 17, 2011
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 BCS Knee System
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

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Device Description

Subject of this Abbreviated Premarket Notification is the Journey II BCS Knee system. The Journey II BCS Knee System is a posterior stabilized total knee system which provides the ability for greater flexion (155°) to those patients who have the anatomical capability to allow a greater flexion range. Components of this premarket notification include:

- Posterior stabilized femoral components which will initially be available in sizes 1-10 in right and left designs in OXINIUM material.
- Posterior stabilized femoral components which will initially be available in sizes 1-9 in right and left designs in cobalt chrome material
- Posterior stabilized 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 BCS articular inserts will be offered in 9-21 mm thicknesses and manufactured from cross-linked polyethylene (XLPE) material and conventional non-cross-linked Ultra-High Molecular Weight Polyethylene (UHMWPE) material.

The Journey II BCS Knee system will use existing cemented Journey tibial tray and patellar components currently used with the Journey BCS Knee System (K042515) and may also be used with existing patellar components of the Genesis II Knee System (K951987).

Technological Characteristics

This 510(k) was prepared in accordance with the Agency's, "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semi-Constrained Total Knee Prostheses," dated April 1993. A review of the mechanical data indicates that the Journey II BCS Knee System is capable of withstanding expected *in vivo* loading without failure. The following mechanical testing of the Journey II BCS Knee system was performed:

- Patellofemoral Contact Area Analysis
- Tibiofemoral Contact Area Analysis
- Static Testing of the Tibial Insert Locking Mechanism

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- Patellofemoral Resistance to Lateral Subluxation
- 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. 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. Smith & Nephew, Inc. Journey II BCS Knee components are indicated for use only with cement and are single use devices.

Substantial Equivalence Information

The substantial equivalence of the Journey II BCS Knee system is based on its similarities in indications for use, design features, and operational principles to the predicate systems listed in the table below.

Table 1: Substantially equivalent predicate devices

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc	High Performance Knee System	K042515	03/14/2005
Smith & Nephew, Inc	Legion Porous Primary Knee System	K073325	12/20/2007
Smith & Nephew, Inc	XLPE Articular Inserts	K071071	09/19/2007
Smith & Nephew, Inc	Genesis II Total Knee System	K951987	08/22/1995
Smith & Nephew, Inc	Genesis II Posterior Stabilized High Flexion Articular Insert	K032295	08/21/2003
Smith & Nephew, Inc	Journey BCS Knee System	K091014	09/29/2009

Conclusion

As previously noted, this Abbreviated 510(k) Premarket Notification is being submitted to request clearance for the Journey II BCS Knee System. 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 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

Smith & Nephew, Inc.
% Ms. Shereen Myers
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1450 Brooks Road
Memphis, Tennessee 38116

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Re: K111711
Trade/Device Name: Journey II BCS Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: June 17, 2011
Received: June 20, 2011

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. 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); 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,

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): K111711

Device Name: Journey II BCS Knee System

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. Smith & Nephew, Inc. Journey II BCS Knee 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 K111711