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We are smith&nephew

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	August 25, 2010
Contact Person and Address:	Shereen Myers, Regulatory Affairs Specialist T (901) 399-6325 F (901) 566-7075
Name of Device:	Smith & Nephew, Inc. Journey CR 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

AUG 2 6 2010

Device Description

Subject of this Abbreviated 510(k) premarket notification is the Journey CR Knee System. The subject device is a cruciate retaining (CR) total knee system which is designed to provide the potential ability for greater flexion to those patients who have the anatomic capability to allow a greater flexion range. Components of this premarket notification include the following components:

- Cruciate retaining femoral components available in sizes 1-10 in right and left designs in OXINIUM material.
- Cruciate retaining femoral components available in sizes 1-9 in right and left designs in cobalt chrome material
- Cruciate retaining articular inserts available in sizes 1-2, 3-4, 5-6, and 7-8 in right and left designs. Journey CR articular inserts will be offered in 9-21mm thicknesses (9, 10, 11, 13, 15, 18, 21) and manufactured from UHMWPE.

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This 510(k) was prepared in accordance with the Agency's, "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semi-Constrained Total Knee Prostheses," dated April 1993.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

- Mechanical testing, removal torque, push-out and torque to failure of the Journey CR femoral lugs
- Static testing of the Journey CR tibial insert locking mechanism
- Tibiofemoral contact area analysis

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- Tibiofemoral constraint testing
- Patellofemoral contact area analysis
- Patellofemoral lateral subluxation

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; failed osteotomies, unicompartmental replacement, or total knee replacement.

Smith & Nephew, Inc. Journey CR Knee System components are indicated for use only with cement and are single use devices.

Substantial Equivalence Information

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

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Genesis II Knee System	K951987	8/22/1995
Zimmer	Nexgen Complete Knee Solution Cruciate Retaining (CR)-Flex Femoral Components	K023211	10/17/2002
Smith & Nephew, Inc.	Genesis II Deep Flexion Cruciate Retaining Articular Insert	K041825	7/6/2004
Howmedica, Inc	Triathlon Cruciate Retaining (CR) Total Knee	K040267	5/5/2004
Smith & Nephew	High Performance Knee[1]	K042515	3/14/2005
DePuy Orthopaedics Inc.	Sigma Cruciate Retaining (C/R) Porocoat® Femoral Components	K062654	9/29/2006

Conclusion

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

[1] The High Performance Knee System cleared via K042515 is now marketed by Smith & Nephew as the Journey BCS Knee System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

AUG 2 6 2010

Re: K101499
Trade Name: Journey CR 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: May 27, 2010
Received: June 12, 2010

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

K101499

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K101499

Device Name: Journey CR 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.

Smith & Nephew, Inc. Journey CR 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 801.109) (Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K101499