Summary of Safety and Effectiveness
Smith & Nephew, Inc. JOURNEY® Select Knee System

K093056 #1/2

Contact Person and Address
Jason Sells
Manager, Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 East Brooks Road
Memphis, Tennessee 38116
T (901) 399-5520

Date of Summary: September 28, 2009

DEC 15 2009

Name of Device: Smith & Nephew, Inc. JOURNEY Select Knee System
Common Name: Knee Prosthesis Components
Device Classification Name and Reference: 21 CFR 888.3520 Knee joint femorotibial metal/polymer non-constrained cemented prosthesis; 21 CFR 888.3540 Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis; 21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Device Class: Class II
Panel Code: Orthopaedics 87/ HSX, KRR, and NPJ

Device Description

The Smith & Nephew, Inc. Journey Select Knee System is composed of existing unicompartmental femoral components, patellofemoral implant components, and unicompartmental tibial components previously cleared by FDA. These components may be used in various combinations to create a bicompartmental knee replacement prosthesis and allow the physician to choose the most appropriate option to treat the patient.

Mechanical Testing

A review of the mechanical testing results indicated that the implant components of the Smith & Nephew, Inc. Journey Select Knee System are equivalent to devices currently used clinically and are capable of withstanding expected *in vivo* loading without failure.

Intended Use

The Smith & Nephew, Inc. Journey Select Knee System is intended to be used for those patients whereby conditions exist that may not be solely addressed by a device that treats a single compartment. The Journey Select Knee System is intended to replace the patellofemoral and either the medial or lateral condyle of the knee joint in patients where there is evidence of sufficient sound bone to seat and support the components. Indications include:

1. Post-traumatic arthritis;
2. Degenerative arthritis; and
3. Failed osteotomies and unicompartmental replacement.

These indications will be used for the Journey Select Knee System, whereby a single condyle and patellofemoral regions of the knee have been affected by one or more of these conditions. The implant devices of the Smith & Nephew, Inc. Journey Select Knee System are single use only and are intended for implantation only with bone cement.

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Substantial Equivalence Information

The individual implant devices in the Smith & Nephew, Inc. Journey Select Knee System are existing devices previously cleared by FDA for unicompartmental knee replacement. The Journey Select Knee System is substantially equivalent to the following compartmental knee systems:

- Howmedica Osteonics Stryker® Compartmental Knee System, K052917
- Howmedica Osteonics Stryker® Compartmental Knee System Line Extension, K082567
- DePuy Orthopaedics Graduated Compartmental Knee (GCK), K061648
- DePuy GCK Femoral and Tibial Components, K070849
- DePuy GCK Femoral and Tibial Components, K070267

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC 15 2009

Smith & Nephew, Inc.
% Mr. Jason Sells
1450 Brooks Road
Memphis, Tennessee 38116

Re: K093056
Trade/Device Name: Smith & Nephew, Inc. Journey Select Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: NPJ, HSX, KRR
Dated: September 28, 2009
Received: September 30, 2009

Dear Mr. Sells:

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K093056

Device Name: Smith & Nephew, Inc. JOURNEY® Select Knee System

Indications for Use:

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Prescription Use (Part 21 CFR 801 Subpart D)	X	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)

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

510(k) Number K093056