510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
SMITH & NEPHEW JOURNEY UNICONDYLAR FEMORAL IMPLANTS

K073175

SUBMITTER'S NAME:	Smith & Nephew, Inc., Orthopaedic Division
SUBMITTER'S ADDRESS:	1450 Brooks Road, Memphis, TN 38116
SUBMITTER'S TELEPHONE NUMBER:	901-399-6055
CONTACT PERSON:	Marlon D. Ridley
DATE SUMMARY PREPARED:	December 12, 2007
TRADE OR PROPRIETARY DEVICE NAME:	Smith & Nephew Journey Unicondylar Femoral Implants
Implant COMMON OR USUAL NAME:	Knee Prosthesis
CLASSIFICATION NAME:	21 CFR 8888.3520 Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis.
DEVICE CLASS:	Class II
PANEL CODE:	Orthopedics/87 HSX

DEC 2 0 2007

DEVICE INFORMATION:

A. INTENDED USE:

The Journey Unicondylar Femoral Implant components are indicated for restoring either compartment of a knee that has been affected by the following:

1. Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2. Correction of functional deformity;
3. Revision procedures where other treatments or devices have failed; and
4. Treatment of fractures that are unmanageable using other techniques.

The Journey Unicondylar Femoral Implant components are single use only and are intended for implantation only with bone cement.

B. DEVICE DESCRIPTION:

The Journey Unicondylar Femoral Implant components will consist of various size and hand femoral implants for medial and lateral tibiofemoral compartment replacement. The femoral implants are anatomically shaped and are available in right and left, medial-lateral hand configurations (LL/RM and RL/LM). The femoral implants are offered in sizes 1-7.

C. SUBSTANTIAL EQUIVALENCE INFORMATION:

The Smith & Nephew Journey Unicondylar Femoral Implant components are substantially equivalent to the following commercially available devices with respect to design, overall indications, and materials:

- Smith & Nephew's GENESIS Unicompartmental Knee System (K912735)
- Smith & Nephew's Unicondylar Femoral Component (K030301)
- Zimmer, Inc. Unicompartmental Knee System (K033363)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2007

Zimmer, Inc.
% Mr. Marlon D. Ridley
Regulatory Affairs Specialist
1450 Brooks Rd.
Memphis, TN 38116

Re: K073175
Trade/Device Name: Journey Unicondylar Femoral Implant
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: November 8, 2007
Received: November 13, 2007

Dear Mr. Ridley:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Smith & Nephew Journey Unicondylar Femoral Implant

Indications for Use:
The Journey Unicondylar Femoral Implant components are indicated for restoring either compartment of a knee that has been affected by the following:

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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 General, Restorative, and Neurological Devices

510(k) Number K073175