510(K) Summary AUG - 4 2006

Smith & Nephew Competitor Unicondylar All-Poly Tibial Baseplate Components

SUBMITTER'S NAME:	Smith & Nephew, Inc., Orthopaedic Division
SUBMITTER'S ADDRESS:	1450 East Brooks Road, Memphis, TN 38116
SUBMITTER'S TELEPHONE NUMBER:	901-399-6707
CONTACT PERSON:	Gino J. Rouss
DATE SUMMARY PREPARED:	June 23, 2006
TRADE OR PROPRIETARY DEVICE NAME:	Smith & Nephew Competitor Unicondylar All-Poly Tibial Baseplate Components
COMMON OR USUAL NAME:	Knee Prosthesis
CLASSIFICATION NAME:	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis, 21 CFR 888.3520
DEVICE CLASS:	Class II
PANEL CODE:	HSX Orthopedics Panel/87

A. INTENDED USE:

The Competitor Unicondylar All-Poly Tibial Baseplate Components are indicated for restoring either compartment of a knee that has been affected by the following:

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- correction of functional deformity;
- revision procedures where other treatments or devices have failed; and
- treatment of fractures that are unmanageable using other techniques

The all-poly baseplate components are single use only and are intended for implantation only with bone cement.

B. DEVICE DESCRIPTION:

New unicondylar knee all-poly tibial baseplate components have been designed and developed by Smith & Nephew Orthopaedics. The overall material and design of the all-poly components are based upon the existing Genesis Unicompartmental tibial implants and the existing Mod II Knee System implants cleared under 510(k) Notifications K912735 and K760245, respectively.

C. SUBSTANTIAL EQUIVALENCE INFORMATION:

The Smith & Nephew Competitor Unicondylar All-Poly Tibial Baseplate Components are similar to the following commercially available devices regarding design features, overall indications, and materials:

- Smith & Nephew Genesis Unicompartmental Knee System (K912735)
- Howmedica Osteonics EIUS Unicompartmental Knee System (K033769)
- Smith & Nephew Mod II Knee System (K760245)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 4 2006

Mr. Gino J. Rouss
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthopaedic Division
1450 E. Brooks Road
Memphis, Tennessee 38116

Re: K061779
Trade/Device Name: Competitor Unicondylar All-Poly Tibial Baseplate
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: II
Product Code: HSX
Dated: June 23, 2006
Received: June 26, 2006

Dear Mr. Rouss:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson, M.S.
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): K061779

Device Name: Competitor Unicondylar All-Polyethylene Tibial Baseplate Components

Indications for Use:

The Competitor Unicondylar All-Poly Tibial Baseplate Components are indicated for restoring either compartment of a knee that has been affected by the following:

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- correction of functional deformity;
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- treatment of fractures that are unmanageable using other techniques

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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 General, Restorative, and Neurological Devices

510(k) Number K061779