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Summary of Safety and Effectiveness
Smith & Nephew, Inc.
Unicondylar Femoral Components

FEB 2 5 2003

Contact Person and Address
Kim Kelly
Project Manager, Clinical and Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 East Brooks Road
Memphis, TN 38116
(901) 399-6566

Device Description
The **Unicondylar Femoral Components** are designed for use with tibial components of the Genesis I Knee System. The **Unicondylar Femoral Components** are metal alloy devices processed via a proprietary oxidation process.

Device Classification Name
21 CFR 888.3520 Knee joint femorotibial metal/polymer/non-constrained cemented prosthesis - Class II

Indications for Use
The **Unicondylar Femoral 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 **Unicondylar Femoral Components** are single use only and are intended for implantation with bone cement.

Mechanical and Clinical Data
A review of the mechanical test data indicated that the **Unicondylar Femoral Components** are equivalent to devices currently used clinically and are capable of withstanding expected *in vivo* loading without failure.

Substantial Equivalence Information
The substantial equivalence of the **Unicondylar Femoral Components** is substantiated by its similarities in design features, overall indications, and material composition as existing components distributed by Smith & Nephew, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 5 2003

Ms. Kim P. Kelly
Project Manager, Regulatory and Clinical Affairs
Smith & Nephew, Inc
Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116

Re: K030301
Trade/Device Name: Unicondylar Femoral Component
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: January 28, 2003
Received: January 29, 2003

Dear Ms. Kelly:

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 (301) 594-4639. 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 may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K030301

Unicondylar Femoral Components
Indications Statement

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

5) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
6) correction of functional deformity;
7) revision procedures where other treatments or devices have failed; and
8) treatment of fractures that are unmanageable using other techniques.

The **Unicondylar Femoral Components** are single use only and are intended for implantation with bone cement.

for Mark N Melkerson

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510(k) Number K030301

Concurrence of CDRH, Office of Device Evaluation

Prescription Use Yes OR (Per 21 CFR 801.109) Over-The Counter Use No