K042896

Summary of Safety and Effectiveness

JAN 12 2005

Smith & Nephew, Inc.

Smith & Nephew Hybrid Knee Femoral Components

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 **Smith & Nephew Hybrid Knee Femoral Components** are designed for use with tibial components of the Genesis I Unicondylar Knee System and patellar components of the Genesis II Total Knee System. The components are used to replace the medial condyle and patellofemoral regions of a femoral knee joint.

Device Classification Name

Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis, 21 CFR 888.3530

Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis, 21 CFR 888.3540

Indications for Use

The **Hybrid Knee Femoral Components** are intended to be used for those patients whereby conditions exist that can not be solely addressed by a device that treats a single compartment (i.e. unicondylar or patellofemoral prosthesis) of the knee.

Indications include:

- post-traumatic arthritis;
- degenerative arthritis; and
- failed osteotomies, hemiarthroplasties; and unicompartmental replacement

These indications will be used for the Hybrid Knee Femoral Components, whereby the medial condyle and patellofemoral regions have been affected by one or more of these conditions.

The Hybrid Knee Femoral Components are single use only and are intended for implantation only with bone cement.

Mechanical and Clinical Data

A review of the mechanical test data indicated that the **Smith & Nephew Hybrid Knee 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 **Smith & Nephew Hybrid Knee Femoral Components** is substantiated by its similarities in design features, overall indications, and material composition as existing components of the Genesis I Unicondylar Knee System and Genesis II Total Knee Systems distributed by Smith & Nephew, Inc., as well as other commercially available patellofemoral joint prostheses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2005

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

Re: K042896
Trade/Device Name: Hybrid Knee Femoral Components
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: NPJ
Dated: October 19, 2004
Received: October 20, 2004

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 (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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for 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

Indications for Use

510(k) Number (if known): K042896

Device Name: Hybrid Knee Femoral Components

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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)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K042896