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Summary of Safety and Effectiveness
Smith & Nephew, Inc.
Total Knee Femoral Component

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 **Total Knee Femoral Components** are designed for use with tibial and patellar components of the Genesis II or Profix Total Knee Systems. The **Total Knee Femoral Components** are metal alloy devices processed via a proprietary oxidation process.

Device Classification Name

21 CFR 888.3560 Knee joint patellofemorotibial metal/polymer/metal semi-constrained cemented prosthesis - Class II

Indications for Use

The Total Knee Femoral Components are indicated for rheumatoid arthritis; post-traumatic arthritis; degenerative arthritis; failed osteotomies; hemiarthroplasties, unicompartmental replacement; or total knee arthroplasties. The Total Knee 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 **Total Knee Femoral Components** are equivalent to devices currently used clinically and are capable of withstanding expected *in vivo* loading without failure.

Wear Claims
The following marketing claim will be made for the **Total Knee Femoral Components**:

> " {Total Knee Femoral Components} offer an 85% reduction in aggregate wear rate as compared to cobalt chrome (CoCr) femoral components (0.69 ± 0.52 mm^3/million cycles vs. 4.68 ± 2.30 mm^3/million cycles). Testing was performed in a multi-axial knee joint simulator for a minimum of 6 million cycles per individual test using size 5 Genesis II femoral components as an articulating counterface, size 5 Genesis II UHMWPE tibial inserts, and Hyclone bovine calf serum as a lubricant. UHMWPE tibial inserts were sterilized via ethylene oxide. For each test condition the aggregate wear rates were computed as the slope of the line fit through the averaged data (n=3) after the initial

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wear-in period of 1.94 million cycles (i.e., 1.94 – 6.13 million cycles). The results of in-vitro tests have not been shown to correlate with clinical wear mechanisms."

Substantial Equivalence Information

The substantial equivalence of the **Total Knee Femoral Components** is substantiated by its similarities in design features, overall indications, and material composition as existing components of the Genesis II and Profix Total Knee Systems distributed by Smith & Nephew, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K022010
Trade/Device Name: Total Knee Femoral Components
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: July 22, 2002
Received: July 23, 20002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, 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). 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

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Total Knee Femoral Components
Indications Statement

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for Mark N Milhous

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

510(k) Number K022010

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____ OR (Per 21 CFR 801.109) Over-The Counter Use ____