K030612

page 1 of 1

MAY 27 2003

Summary of Safety and Effectiveness
Smith & Nephew, Inc.
Genesis II Total Knee System

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 porous coated components of the **Genesis II Total Knee System** are designed for use with existing tibial and patellar components and accessories of the Genesis II Total Knee Systems cleared via K951987 and K953274. The subject components are porous coated metal alloy devices.

Device Classification Name

21 CFR 888.3565 (MBH) Knee joint patellofemorotibial metal/polymer/metal semi-constrained uncemented prosthesis - Class II

Indications for Use

The porous components of the **Genesis II Total Knee System for Uncemented Use** are single use devices for use without cement. The devices are indicated for:

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity levels are compatible with an adequate long-term result.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. The posterior stabilized knee system is designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

Mechanical and Clinical Data

A review of the mechanical test data indicated that the porous components of the **Genesis II Total Knee System** are equivalent to devices currently available and are capable of withstanding expected *in vivo* loading without failure.

Substantial Equivalence Information

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2003

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

Re: K030612
Trade/Device Name: Genesis II Total Knee System
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: MBH
Dated: February 25, 2003
Received: February 26, 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.

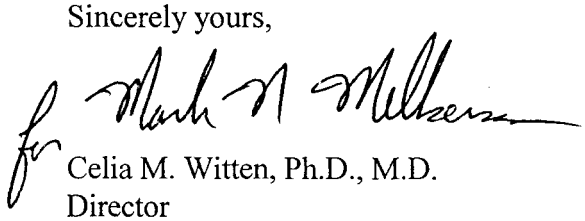
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4659. 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,



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

K030612

Genesis II Total Knee System
Indications Statement

The porous components of the **Genesis II Total Knee System** are single use devices for use without cement. The devices are indicated for:

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity levels are compatible with an adequate long-term result.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. The posterior stabilized knee system is designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

for Mark N Melkerson

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

510(k) Number K030612

Concurrence of CDRH, Office of Device Evaluation

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