OCT 1 5 2003

K032683

510(K) SUMMARY

SMITH & NEPHEW GENESIS II KNEE SYSTEM

SUBMITTER'S NAME:	Smith & Nephew, Inc., Orthopaedic Division
SUBMITTER'S ADDRESS:	1450 Brooks Road, Memphis, TN 38116
SUBMITTER'S TELEPHONE NUMBER:	901-399-5153
CONTACT PERSON:	Janet Johnson Akil
DATE SUMMARY PREPARED:	August 28, 2003
TRADE OR PROPRIETARY DEVICE NAME:	Genesis II Total Knee System
COMMON OR USUAL NAME:	Total Knee Prosthesis
CLASSIFICATION NAME:	Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
DEVICE CLASS:	Class II
PANEL CODE:	Orthopedics/87

DEVICE INFORMATION:

A. INTENDED USE:

The Genesis II Total Knee System is 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.

The Genesis II Total Knee System includes porous and porous plus HA coated devices which are indicated for use with or without bone cement, and are single use devices.

B. DEVICE DESCRIPTION:

Genesis II Porous Plus HA Knee System Components contain an HA coating on the porous coated areas of the devices. These porous plus HA components are designed for use with existing knee components contained within the Genesis II Total Knee System.

C. SUBSTANTIAL EQUIVALENCE INFORMATION:

Genesis II Porous Plus HA Knee System Components are substantially equivalent to the Smith & Nephew Genesis II Knee System for Uncemented Applications (K030612), Smith & Nephew Synergy HA on Porous Hip Stems (K002996), and Smith & Nephew Echelon Porous Plus HA Hip Stems (K023302).

D. SUMMARY OF TECHNOLOGICAL COMPARISON:

The intended use, designs, and materials of the Genesis II Total Knee System are substantially equivalent to the predicate components found in the original Genesis II System submissions previously cleared by FDA. Summary report results indicate that the subject devices meet the requirements of the applicable FDA guidance documents.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2003

Ms. Janet Johnson Akil
Director, Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 E. Brooks Road
Memphis, TN 38116

Re: K032683
Trade/Device Name: Genesis II Porous Plus HA 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: August 28, 2003
Received: August 29, 2003

Dear Ms. Akil:

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.

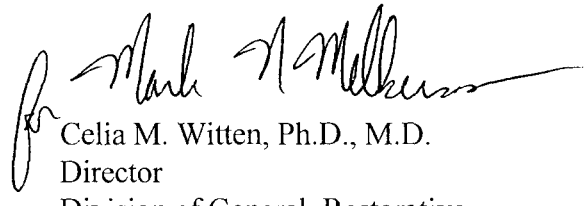
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

K032683

510(k) Number (if known):

Device Name: Genesis II Knee System

Indications For Use:

The Genesis II Total Knee System is 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.

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The Genesis II Total Knee System includes porous and porous plus HA coated devices which are indicated for use with or without bone cement, and are single use devices.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhous

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

510(k) Number K032683