Orthopaedic Division
Smith & Nephew, Inc.
1450 Brooks Rd., Memphis, TN 38116 U.S.A.
901-396-2121, For information: 1-800-821-5700
For orders and order inquiries: 1-800-238-7538

Smith+Nephew

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510(k) Summary of Safety and Effectiveness

Submitter's name:	Smith & Nephew, Inc., Orthopaedic Division
Submitter's address:	1450 Brooks Road, Memphis, TN 38116
Submitter's telephone number:	Direct phone: **901-399-6487** or FAX: **901-398-5146**
Contact person:	David Henley, Senior Clinical/Regulatory Affairs Specialist
Date summary prepared:	March 15, 2002
Trade or proprietary device name:	UHMWPE Components of the *Genesis*, the *Genesis II*, and the *Profix Knee Systems* Sterilized with the VHP® Sterilization Process
Common or usual name:	Genesis, Genesis II, and Profix Knee System UHMWPE Components
Classification name:	21 CFR 888.3560, knee joint patellofemorotibial polymer/metal/polymer, semi-constrained cemented prosthesis

Substantially Equivalent Legally Marketed Devices

- The Genesis Knee System – Smith & Nephew, Inc.
- The Genesis II Knee System – Smith & Nephew, Inc.
- The Profix Knee System – Smith & Nephew, Inc.

Device Description

There have been no changes in indications for use, design, or material property changes to any Genesis, Genesis II, or Profix Knee System UHMWPE components that will be sterilized using the VHP® process.

The VHP® sterilization process uses hydrogen peroxide (H_2O_2) vapor for sterilization Genesis Knee System, Genesis II Knee System, and Profix Knee System components (tibial articular inserts, all polyethylene tibial bases, patellar, and flex-lok pegs) manufactured from UHMWPE using the Century SL VHP® Sterilizer. Sterilization is achieved by a series of H_2O_2 gas injections at deep vacuum set points. Aeration of the medical devices after sterilization is conducted by a series of chamber evacuations.

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Device Intended Use

Components in the Genesis, Genesis II, and Profix Knee Systems are indicated for:

1) Rheumatoid arthritis; 2) Post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level 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. 5) The constrained knee system is designed for use in patients in primary and revision surgeries, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligaments) are absent or incompetent.

The devices that are the subject of this premarket notification are intended for cemented use only and are for single use only.

The Orthopaedic Division of Smith & Nephew, Inc. will utilize the VHP® sterilization process to terminally sterilize all orthopaedic implant components manufactured from UHMWPE material in the *Genesis Knee System,* the *Genesis II Knee System,* and the *Profix Knee System* (tibial articular inserts, all polyethylene tibial bases, patellae, and flex-lok pegs).

Technological Characteristics

The VHP® sterilization process is similar to the predicate sterilization processes listed above. Both of these predicate sterilization processes are intended to terminally sterilize orthopaedic implants/medical devices to a Sterility Assurance Level (SAL) of 10^{-6}. When compared to the VHP® process, the predicate processes also have similar technological characteristics.

Performance Characteristics

The Orthopaedic Division of Smith & Nephew, Inc. has conducted numerous tests as supporting evidence that the VHP® sterilization process is qualified for sterilization of all UHMWPE orthopaedic implants in the Genesis, Genesis II, and Profix Knee Systems by demonstrating the following:

- Microbicidal effectiveness of the vaporized hydrogen peroxide
- The effects of the VHP® sterilization cycle on UHMWPE material and the materials in which the product is packaged
- Process validation efforts to demonstrate that the VHP® sterilization process is effective and reproducible resulting in a SAL of at least 10^{-6}

Test results demonstrated that the VHP® sterilization process is capable of terminally sterilizing UHMWPE orthopaedic implants and verifies achievement of a SAL of 10^{-6}. The VHP® sterilization process was also demonstrated to be safe, reproducible, predictable and effective in sterilizing UHMWPE orthopaedic implants packaged and sealed in Tyvek®/Mylar® pouches.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 5 2002

Mr. David Henley
Senior Clinical/Regulatory Affairs Specialist
Orthopedic Division
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

Re: K012778
Trade/Device Name: UHMWPE Components of the Genesis, the Genesis II, and the Profix Knee Systems
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: December 14, 2001
Received: December 17, 2001

Dear Mr. Henley:

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

Premarket Notification
Indications Enclosure

510(k) Number (if known): K012778

Device Name: UHMWPE Components of the Genesis, Genesis II, and Profix Knee Systems Sterilized with the VHP® Sterilization Process

Indications for Use:

Components in the Genesis, Genesis II, and Profix Knee Systems are indicated for:

1) Rheumatoid arthritis; 2) Post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level 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. 5) The constrained knee system is designed for use in patients in primary and revision surgeries, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligaments) are absent or incompetent.

The devices that are the subject of this premarket notification are intended for cemented use only and are for single use only.

The Orthopaedic Division of Smith & Nephew, Inc. will utilize the VHP® sterilization process to terminally sterilize all orthopaedic implant components manufactured from UHMWPE material in the following product systems:

- *Genesis Knee System* (i.e. tibial articular inserts, all polyethylene tibial bases, patellae, and flex-lok pegs)
- *Genesis II Knee System* (i.e. tibial articular inserts, all polyethylene tibial bases, patellae, and flex-lok pegs)
- *Profix Knee System* (i.e. tibial articular inserts, all polyethylene tibial bases, patellae)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhem

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

510(k) Number K012778

Prescription Use ✓ OR Over-the-Counter Use N/A
(Per 21 CFR 801.109) (Optional Format 1-2-96)