K953274

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

Substantial Equivalent Information

The Genesis II Knee System is similar to the following knee systems:

1. Genesis I Total Knee System - Smith & Nephew Richards Inc.
2. NexGen Knee System - Zimmer
3. R.F.C. Modular Knee System - Johnson & Johnson
4. Whiteside Ortholoc II Modular Knee System - Wright Medical Technology, Inc.
5. AMK/Coordinate Knee System - Depuy
6. Advantim Knee System - Wright Medical Technology, Inc.
7. Kinemax Plus Stabilizer Knee System - Howmedica
8. S-ROM Modular Knee System - Joint Medical Products

All of the devices listed above are indicated for total knee replacement and are similar in design to the Genesis II Knee System. The safety and effectiveness of the Genesis II Knee System is based on the long history of use of these devices in the market place.

Device Description

The Genesis II Porous Tibial Trays and Revision Knee consists of the following components: Conversion Module with Taper, Distal Femoral Wedge, Stacked Distal Femoral Wedge, Long Stem Extensions, Femoral Flex-Lok Pegs, Porous Titanium Tibial Tray with and without holes, Porous Spiked Titanium Tibial Tray with and without holes, and the All Poly P/S Tibial Component. The Conversion Module with Taper is manufactured from Co-Cr-Mo. Wedges and Long Stem Extensions are manufactured from Ti-6Al-4V. The tibial trays are manufactured from Ti-6Al-4V with a C.P. Titanium porous coating. The All Poly P/S Tibial Component and the Flex Lok Pegs are manufactured from UHMW PE.

Indications for Use

The Genesis II Revision System is used for primary and revision surgeries with the following indications:

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.

The Genesis II Total Knee System is indicated for use only with cement and is a single use device.

Mechanical Testing

Mechanical testing was performed according to the requirements in the knee draft guidance document. Following is a list of the testing that supports the safety and effectiveness for the Genesis II Knee System: device constraint, device contact area, tibial tray fatigue, and porous coating characterization. All of the test results indicate that the Genesis II Knee System is capable of withstanding *in vivo* loading without failure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 1996

Mr. Thomas L. Craig
Director, Clinical and Regulatory Affairs
Smith & Nephew Richards Inc.
1450 Brooks Road
Memphis, TN 38116

Re: K953274
Genesis II Porous Tibial Trays and
Revision Knee Components
Regulatory Class: II
Product Code: JWH
Dated: November 6, 1995
Received: November 7, 1995

Dear Mr. Craig:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). This decision is based on this device being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Act and the following limitations:

1. The thinnest tibial component available is the nominal "9mm" sized component, which has a minimum polyethylene thickness under the condyles of 9.6mm.

2. This device may not be labeled or promoted for non-cemented use.

3. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.

4. Any non-cemented fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation must receive

approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice regarding labeling for your device in accordance with 21 CFR Part 801, promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Kimber Richter

Kimber C. Richter, M.D.
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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