

K9-1087

AUG 22 1995

**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 Total Knee System - Smith & Nephew Richards Inc.
2. Profix Total Knee System - Smith & Nephew Richards Inc.
3. NexGen Knee System - Zimmer
4. P.F.C. Modular Knee System - Johnson & Johnson
5. Omrifit Total Knee System - Osteonics
6. Whiteside Ortholoc II Modular Knee System - Dow Corning Wright
7. AMK/Coordinate Knee System - Depuy

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 Knee System consists of the following components: Porous Cruciate Retaining Femoral Component, Non-Porous Cruciate Retaining Femoral Component, Low Demand Femoral Component, Porous Posterior Stabilized Femoral Component, Non-Porous Posterior Stabilized Femoral Component, Cruciate Retaining Tibial Insert, Dished Tibial Insert, Posterior Stabilized Tibial Insert, Titanium Tibial Tray, Cobalt Chromium Tibial Tray, All Polyethylene Tibial Component, Posterior Femoral Wedge, Angled Hemi Tibial Wedge, Stepped Hemi Tibial Wedge, Medial-Lateral Tibial Wedge, Biconvex Patellar Component, Resurfacing Patellar Component, All Polyethylene Patellar Component with Flex-Lok Peg, and Revision Biconvex Patellar Component. The femoral components are manufactured from Co-Cr-Mo and available with and without a Co-Cr-Mo porous coating. The porous coating on the femoral component is the same as that on the Genesis I Femoral Component. The tibial inserts, all poly tibial components, patellar components, and Flex Lok Pegs are manufactured from UHMW PE. Wedges are manufactured from Ti-6Al-4V.

EXHIBIT 3  
EXHIBIT 4  
EXHIBIT 5

## Indications for Use

The Genesis II Knee System is 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.

The Genesis III 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, patello-femoral resistance to lateral subluxation, static and fatigue tibial component lock strength testing, static wedge testing, 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

AUG 22 1995

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K951987  
Genesis II Total Knee System  
Regulatory Class: II  
Product Code: JWH  
Dated: April 26, 1995  
Received: April 27, 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 insert available is the nominal "9mm" sized insert, which has a minimum polyethylene thickness under the condyles of 6.7mm, and the thinnest all polyethylene tibial component available is the nominal "9mm" sized component, which has a 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 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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