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

K952271

SEP - 8 1995

Substantial Equivalence Information

The Genesis Constrained System is similar to the following knee systems

1. Genesis Posterior Stabilized Knee System - Smith & Nephew Richards
2. Insall/Burstein Constrained Condylar Knee - Zimmer
3. P.F.C. Modular Knee System - Johnson & Johnson
4. Kinemax Plus Total Knee System - Howmedica
5. Omnifit Total Knee System - Osteonics
6. S-ROM Modular Knee System - Joint Medical Product
7. Coordinate Revision Knee System - Depuy
8. Advantim Total Knee System - Wright Medical Technology

All of the devices listed above are similar in design to the Genesis Constrained System. The safety and effectiveness of the Genesis Constrained System is based on the long history of use of these devices in the market place.

Device Description

The Genesis Constrained System consists of a femoral conversion module, tibial insert, and femoral intramedullary stem. The femoral conversion module is manufactured from cobalt-chromium-molybdenum (ASTM F 75) and attaches to the Genesis femoral component via fixation lugs. The femoral conversion module has a box-like design to constrain motion. The tibial insert is manufactured from ultra-high-molecular-weight polyethylene (ASTM F 648). The tibial insert has a centrally located post which engages with the femoral conversion module. The Femoral I/M Stem is manufactured from Ti-6Al-4V (ISO 5832/3) and attaches to the femoral conversion module by a morse taper interlock.

Indications for Use

The Genesis Constrained 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 Genesis Constrained System is designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are absent or incompetent.

The Genesis Constrained System is indicated for use with cement and is a single use device.

Mechanical Testing

Mechanical testing was performed according to the requirements in the knee draft guidance document. The following is a list of the testing that supports the safety and effectiveness for the Genesis Constrained System: device constraint, device contact area, femoral construct fatigue, and fatigue testing of the tibial insert post and locking mechanism. All of the test results indicate that the Genesis Constrained System is capable of withstanding *in vivo* loading without failure.

Exhibit 5

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

SEP - 8 1995

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

Re: K952271
Genesis Constrained System (GCS)
Regulatory Class: II
Product Code: JWH
Dated: May 12, 1995
Received: May 15, 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 "10mm" sized insert, which has a minimum polyethylene thickness under the condyles of 6.98mm.

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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