K954087

AUG - 8 1995

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

The Genesis Posterior Stabilized (P/S) Knee System is indicated for restoring a knee that has been damaged by rheumatoid arthritis, post-traumatic arthritis, osteoarthritis, failed osteotomies or hemi-arthroplasties where the anterior and posterior cruciate ligaments are absent or incompetent. The Genesis P/S Knee System is indicated for use with cement and is a single use device.

The Genesis P/S Knee System is substantially equivalent to the following products: Smith & Nephew Richards' RMC Posterior Stabilized Knee System, Zimmer's Insall/Burstein Posterior Stabilized Knee System, Johnson & Johnson's P.F.C. Modular Knee System, Howmedica's Kinemax Plus Total Knee System, Osteonics' Omnifit Total Knee System, Joint Medical Product's S-ROM Modular Knee System, Dow Corning Wright's Whiteside Ortholoc II Modular Knee System, Biomet's AGC Total Knee System, and Depuy's Coordinate Knee System. The safety and effectiveness of the Genesis P/S Knee System is based on the long history of use of these devices in the market place.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 1995

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

Re: K946088
Genesis Posterior Stabilized Knee System
Regulatory Class: II
Product Code: JWH
Dated: June 5, 1995
Received: June 6, 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). You may, therefore, market your device subject to the general controls provisions of the Act and the following limitation: all labeling for this device system, including the package label and labeling included within the package, must prominently state that the Genesis Posterior Stabilized (P/S) Knee System is intended only for cemented use.

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 (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,

Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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