K022902

OCT 0 2 2002

510(k) SUMMARY

Smith & Nephew Hip System

In conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the **Smith & Nephew Hip System**.

Submitter's name: **Submitter's address:**	Smith & Nephew, Inc., Orthopaedic Division 1450 Brooks Road Memphis, TN 38116
Submitter's telephone number:	901-399-6487
Contact person: **Date Summary prepared:**	David Henley August 30, 2002
Trade or proprietary name:	**Smith & Nephew Hip System**
Common or usual name:	Cross-Linked UHMWPE Acetabular Liner Components; Cobalt Chrome Femoral Heads
Classification name:	21 CFR 888.3358 Hip Joint metal/polymer/metal semi-constrained porous-coated uncemented prostheses, Class II
Device Product Code and Panel Code:	Orthopedics/87

Substantially Equivalent Legally Marketed Devices

Components comprising the **Smith & Nephew Hip System** are substantially equivalent to Sulzer Inter-Op Durasul Acetabular Liner Inserts and femoral heads that were cleared for market under K993259 and K002575.

Device Description

The **Smith & Nephew Hip System** is comprised of cross-linked UHMWPE acetabular liners and cobalt chrome femoral heads. The acetabular liners are designed to mate to previously cleared Smith & Nephew Reflection metal acetabular shells. The cobalt chrome femoral heads are designed to function with the subject acetabular liners and to mate with Smith & Nephew femoral hip stems identified in this Special 510(k) Premarket Notification. The intended use, type of interface, and design features of the components comprising the **Smith & Nephew Hip System** are identical to other Smith & Nephew predicate devices identified in this submission.

Device Intended Use

Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis and diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; non-union; femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity. **Smith & Nephew Hip System** components are designed for single use only.

Technological and Performance Characteristics

The components comprising the **Smith & Nephew Hip System** are similar to predicate devices manufactured by Smith & Nephew and previously cleared for market. Thus, the intended use, material, and design features of these components are identical to the predicate devices identified in this submission. The safety and effectiveness for the subject devices are adequately supported by test data, material information, and substantial equivalence information provided in this Special 510(k) Premarket Notification. Design Verification Tests results indicate that the subject devices meet the requirements of the applicable guidance documents.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 02 2002

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

Re: K022902
Trade/Device Name: Linked UHMWPE Acetabular Liner Components and Cobalt Chrome Femoral Head
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint, Metal/Polymer/Metal, Semi-Constrained, Porous-Coated, Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: August 30, 2002
Received: September 3, 2002

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 and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications Enclosure

510(k) Number (if known): K022902

Device Name: **Smith & Nephew Hip System**

Indications for Use:

Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis and diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; non-union; femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Smith & Nephew Hip System components are intended for single use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A Millerson

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

510(k) Number K022902

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-the-Counter Use No
(Optional Format 1-2-96)