OCT 02 2002

K022958

Smith & Nephew, Inc.
Summary of Safety and Effectiveness :Total Hip Femoral Heads & Liners

Contact Person and Address
Kim Kelly
Project Manager, Clinical and Regulatory Affairs
Smith & Nephew, Inc., Orthopaedics Division
1450 East Brooks Road
Memphis, TN 38116
(901) 399-6566

Date of Summary: September 5, 2002

Name of Device: Total Hip Femoral Heads & Liners
Common Name: Femoral heads and acetabular liners

Device Classification Name
21 CFR 888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis:Class II
21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis: Class II
21 CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis: Class II

Substantial Equivalence Information
The **Total Hip Femoral Heads** are substantially equivalent to Sulzer Inter-Op CoCr heads (K993259), Osteonics Alumina C-Taper Heads (K003391), and currently marketed heads distributed by Smith & Nephew. The **Total Hip Liners** are substantially equivalent to Sulzer Inter-Op Durasul Acetabular Inserts (K993259 & K002575), DePuy Duraloc Acetabular Cup System (K010171), and Smith & Nephew crosslinked polyethyelene liners.

Device Description
The **Total Hip Femoral Heads** are zirconium alloy or alumina ceramic devices designed for use with both titanium and cobalt chromium alloy femoral components with a 12/14 taper. These heads are to be used with the appropriate sized crosslinked polyethylene **Total Hip Liners. Total Hip Liners** are to be used with corresponding titanium acetabular shells.

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; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion; femoral neck fracture and trochanteric fractures of the proximal femur with heads involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity. The **Total Hip Femoral Heads & Liners** are designed for single use only and may be used as part of cemented or uncemented total hip arthroplasty.

Technological & Performance Characteristics:
The **Total Hip Femoral Heads and Liners** are similar to currently marketed femoral heads and liners. These components share the same intended use, material, and design features of one or more of the above mentioned predicates. A review of the mechanical and wear test data indicated that the **Total Hip Femoral Heads and Liners** are equivalent to devices currently on the market and are capable of withstanding expected *in vivo* loading without failure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Kim P. Kelly
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Smith and Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

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Re: K022958
Trade/Device Name: Total Hip Femoral Heads and Liners
Regulation Number: 21 CFR 888.3350, 888.3353, 888.3358
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis; Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis; Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: JDI, LZO, LPH
Dated: September 5, 2002
Received: September 6, 2002

Dear Mr. Kelly:

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" (21 CFR 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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Total Hip Femoral Heads & Liners
Indications Statement

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; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion; femoral neck fracture and trochanteric fractures of the proximal femur with heads involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

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

510(k) Number K022958