K030766
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Summary of Safety and Effectiveness
Smith & Nephew, Inc.
Oxinium Femoral Heads: Additional Claims

Contact Person and Address

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1450 East Brooks Road
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Device Description

The **Oxinium Femoral Heads** are designed for use with femoral stems and acetabular components distributed by Smith & Nephew. The **Oxinium Femoral Heads** are metal alloy devices processed via a proprietary oxidation process.

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

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 **Oxinium Femoral Heads** are for single use only and can be used as part of cemented or uncemented total hip arthroplasty.

Mechanical and Clinical Data

A review of the mechanical test data indicated that the **Oxinium Femoral Heads** are equivalent to devices currently used clinically and are capable of withstanding expected *in vivo* loading without failure.

Wear Particle Claims

The following marketing claims will be made for **Oxinium Femoral Heads**.

1) Oxinium Femoral Heads generate 28% less crosslinked polyethylene particles as compared to equivalent sized CoCr femoral heads. Testing was performed in a multi-axial hip joint simulator for five million cycles per individual test using a 32mm, +0 offset Oxinium Femoral Head or Smith & Nephew Universal CoCr femoral head articulating counterface; a Reflection Crosslinked (10Mrad) Acetabular Liner (32mm I.D., 54-56 mm O.D., 11mm thickness, Size "F", 20° overhang), and Hyclone Modified Alpha Serum lubricant. The testing conducted did not detect any polyethylene particles with diameters less than 0.05 μm. The results of *in vitro* tests have not been shown to correlate with clinical wear mechanisms or performance.

2) Oxinium Femoral Heads generate 30% less conventional polyethylene particles as compared to equivalent sized CoCr femoral heads. Testing was performed in a multi-axial hip joint simulator for five million cycles per individual test using a 32mm, +0 offset Oxinium Femoral Head or Smith & Nephew Universal CoCr femoral head articulating counterface; a Reflection Acetabular Liner (32mm I.D., 54mm O.D., 11mm thickness, 20° overhang), and Hyclone Modified Alpha Serum lubricant. The testing conducted did not detect any polyethylene particles with diameters less than 0.05 μm. The results of *in vitro* tests have not been shown to correlate with clinical wear mechanisms or performance.

3) Oxinium Femoral Heads generate 63% less crosslinked polyethylene particles as compared to equivalent sized CoCr femoral heads under roughened conditions [1]. Testing was performed in a multi-axial hip joint simulator for five million cycles per individual test using a 32mm, +0 offset Oxinium Femoral Head or Smith & Nephew Universal CoCr femoral head articulating counterface; a Reflection Crosslinked (10Mrad) Acetabular Liner (32mm I.D., 54-56 mm O.D., 11mm thickness, Size "F", 20° overhang), and Hyclone Modified Alpha Serum lubricant. The testing conducted did not detect any crosslinked polyethylene particles with diameters less than 0.05 μm. The results of *in vitro* tests have not been shown to correlate with clinical wear mechanisms or performance.

4) Oxinium Femoral Heads generate 45% less conventional polyethylene particles as compared to equivalent sized CoCr femoral heads under roughened conditions [1]. Testing was performed in a multi-axial hip joint simulator for five million cycles per individual test using a 32mm, +0 offset Oxinium Femoral Head or Smith & Nephew Universal CoCr femoral head articulating counterface; a Reflection Acetabular Liner (32mm I.D., 54mm O.D., 11mm thickness, 20° overhang), and Hyclone Modified Alpha Serum lubricant. The testing conducted did not detect any crosslinked polyethylene particles with diameters less than 0.05 μm. The results of *in vitro* tests have not been shown to correlate with clinical wear mechanisms or performance.

[1] The roughened condition test is conducted in an effort to evaluate the effects of third body wear on the wear performance of total joint devices. The femoral heads are tumbled with abrasive media prior to testing. This method has been found to simulate the scratch patterns seen on clinically retrieved femoral heads.

Substantial Equivalence Information

The substantial equivalence of the **Oxinium Femoral Heads** is substantiated by its similarities in design features, overall indications, and material composition as existing femoral head components distributed by Smith & Nephew, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2003

Mrs. Kim P. Kelly, MS
Project Manager, Regulatory & Clinical Affairs
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116

Re: K030766
Trade/Device Name: Oxinium Femoral Heads
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: II
Product Code: JDI, LZO, LPH
Dated: May 1, 2003
Received: May 2, 2003

Dear Mrs. 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Oxinium Femoral Heads: Additional Claims
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. The **Oxinium Femoral Heads** are for single use only and can be used as part of cemented or uncemented total hip arthroplasty.

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030766

Concurrence of CDRH, Office of Device Evaluation

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