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510(k) Summary of Safety and Effectiveness
Smith & Nephew Oxinium DH Femoral Heads

AUG 21 2008

Contact Person and Address
Jason Sells
Project Manager, Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 E. Brooks Road
Memphis, Tennessee 38116
(901) 399-5520

Date of Summary: July 21, 2008

Name of Device: Smith & Nephew Oxinium DH Femoral Heads
Common Name: Femoral Head
Device Classification Name and Reference: 21 CFR 888.3350 (Hip joint metal/polymer semi-constrained cemented prosthesis – Class II); and 21 CFR 888.3358 (Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis – Class II)
Device Product Code: JDI, LPH

Device Description
The Oxinium DH femoral heads are designed for use with existing Smith & Nephew hip stems featuring a 12/14 taper and will articulate against existing acetabular shell and liner constructs. A complete list of hip stems and acetabular components intended for use with the Oxinium DH heads is provided in Tables 1 and 2, respectively. The overall design of the Oxinium DH femoral heads is based upon the existing Total Hip 12/14 Taper Femoral Heads cleared via K021673 and the Oxinium femoral heads cleared as part of K022958 for Total Hip Femoral Heads & Liners.

Table 1: Previously cleared Smith & Nephew hip stems with a 12/14 taper

Description	510(k)	Clearance Date
Echelon (Revision) Hip Stems – Porous and Non-porous	K963486	11/27/96
Echelon Primary Hip Stems	K983834	2/24/99
Echelon Hip Stems – HA Coated	K023302	10/25/02
Synergy (Tapered) Hip Stems – Porous and Non-porous	K963509	1/27/97
Synergy (Tapered) Hip Stems – HA Press-fit	K970337	2/28/97
Synergy Cemented Hip Stems	K990369	3/12/99
Synergy Porous Size 8 Hip Stem	K991485	7/12/99
Synergy HA Coated Porous Hip Stems	K002996	12/11/00
Spectron Hip Stems	K970351	2/28/97
Smith & Nephew Modular Hip (Emperion)	K042127	11/19/04
Smith & Nephew Modular Hip (Emperion) – Line Additions	K052426	12/07/05
Platform Hip Stem	K052275	12/07/05
Anthology Hip Stems	K052792	10/07/05
Smith & Nephew Patient Matched Hip Stem (PMHS)	K053246	7/12/06
Smith & Nephew MIS Hip Stem	K072417	1/10/08
Smith & Nephew MIS Hip Stem with StikTite	K080625	5/8/08
SL-PLUS Standard and Lateral Hip Stems	K072852	6/9/08

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Table 2: Previously cleared Smith & Nephew acetabular liners and shells

Description	510(k)	Clearance Date
Reflection Acetabular Cup System (formerly the Modular Acetabular Cup System) (cemented use)	K920430	7/21/92
Reflection Acetabular Components (uncemented use)	K932755	5/6/94
Reflection Dual Dimension Shell (Interfit Shells)	K960094	3/27/96
Hydroxyapatite Reflection Acetabular Shells (Interfit HA coated shell)	K990666	8/6/99
Reflection Cross-linked UHMWPE Acetabular Liners: 5 Mrad Irradiation Dosage	K991026	10/28/99
Reflection Cross-linked UHMWPE Acetabular Liners: 10 Mrad Irradiation Dosage	K002747	12/15/00
Smith & Nephew Hip System – Reflection 36 mm XLPE Liners	K022902	10/2/02
Reflection 3 Acetabular System	K061253	5/31/06
Reflection 3-Hole Shell with Asymmetric Porous Coating	K060630	6/14/06
Reflection 3 Acetabular System	K070756	6/6/07

Mechanical Testing

A review of the mechanical testing results indicated that the Smith & Nephew Oxinium DH femoral heads are equivalent to devices currently used clinically and are capable of withstanding expected *in vivo* loading without failure.

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; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, 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 Oxinium DH femoral heads are for single use only.

Substantial Equivalence Information

The Smith & Nephew Oxinium DH femoral heads are similar in overall design, indications, and materials to the Total Hip 12/14 Taper Femoral Heads cleared via K021673 and the Oxinium femoral heads cleared as part of K022958 for Total Hip Femoral Heads & Liners.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 - 2008

Smith & Nephew, Inc.
% Mr. Jason Sells
Project Manager, Regulatory Affairs
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K081566
Trade Name: Oxinium DH Femoral Heads
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH, JDI
Dated: July 21, 2008
Received: July 22, 2008

Dear Mr. Sells:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name: Oxinium DH Femoral Heads

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 head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity. Smith & Nephew Oxinium DH femoral heads are for single use only.

Prescription Use	X	AND/OR	Over-The-Counter Use	
(Part 21 CFR 801 Subpart D)			(21 CFR 807 Subpart C)	

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K081566