K093363

JAN 26 2010

510(k) Summary
CoCr and Oxinium Femoral Heads and R3 XLPE Liners

Submitter's Name:	Smith & Nephew, Inc., Orthopaedic Division
Submitter's Address:	1450 Brooks Road, Memphis, TN 38116
Submitter's Telephone Number:	901-399-5340
Contact Person:	Megan Bevill
Date Summary Prepared:	January 26, 2010
Trade or Proprietary Device Name:	CoCr and Oxinium Femoral Heads and R3 XLPE Liners
Common or Usual Name:	Femoral Heads and Acetabular Liners
Classification Name:	21 CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87/MBL

Device Description
Subject of this Traditional Premarket Notification are CoCr and Oxinium Femoral Head line additions in sizes 40 and 44mm and R3 XLPE Acetabular Liner line additions with inner diameters of 40 and 44mm.

Intended Use and Indications
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 or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

Substantial Equivalence
The subject CoCr and Oxinium Femoral Heads and R3 XLPE Liners are substantially equivalent to the predicate devices listed in the table below.

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	36mm CoCr Femoral Heads	K022902	10/2/02
Smith & Nephew, Inc.	36mm Oxinium Femoral Heads	K022958	10/2/02
Smith & Nephew, Inc.	Unipolar Femoral Heads	K896580 K934353	2/15/90 4/25/94
Smith & Nephew, Inc.	Modular Femoral (Hemi) Heads	K062408	9/12/06
Smith & Nephew, Inc.	Reflection 3 Acetabular System	K061253 K070756	5/31/06 6/6/07
Smith & Nephew, Inc.	Reflection XLPE Acetabular Liners	K071160	10/5/07
Stryker Orthopaedics	Trident Hip System	K061434	8/22/06
Depuy Orthopaedics, Inc.	Pinnacle Altrx Acetabular Cup Liner	K062148	10/24/06

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Smith & Nephew Inc., Orthopaedic Division
Ms. Megan Bevill
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

JAN 2 6 2010

Re: K093363
Trade/Device Name: CoCr and Oxinium Femoral Heads and R3 XLPE Liners
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: MBL
Dated: October 26, 2009
Received: October 28, 2009

Dear Ms. Bevill:

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 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K093363

Device Name: CoCr and Oxinium Femoral Heads and R3 XLPE Liners

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 or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

The Reflection 3 Acetabular System is for single use only and is intended for cementless use.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093363