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MAY - 8 2008

Smith & Nephew, Inc.
Summary of Safety and Effectiveness
MIS Hip Stem

Contact Person and Address
Rishi Sinha
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthopaedic Reconstruction
1450 Brooks Road
Memphis, TN 38116
(901)399-6054

Date of Summary: 03/4/2008

Name of Device: Smith & Nephew MIS Hip Stem with Stiktite
Common Name: MIS Hip Stem

Device Description

The Smith & Nephew MIS Stem is a straight, tapered, proximally loading stem designed to match the geometry of the femur. The stems are proportionally sized and shaped in sizes 1 through 9 and have modular neck options to address patient anatomy. The stems are manufactured from titanium alloy (Ti-6Al-4Vl and the necks are manufactured from Cobalt Chrome. Each femoral stem is proximally coated with Smith & Nephew's Stiktite porous coating.

Device Classification

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 uncemented use in 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 osteomyelitits 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 MIS Hip Stem components are intended for single use only and are to be implanted without bone cement.

Substantial Equivalence Information

The overall design of the Smith & Nephew MIS Hip Stem is substantially equivalent to previously cleared devices listed below.

Manufacturer	Description	510(k)	Clearance Date
Smith & Nephew, Inc.	MIS Hip Stem	K072417	1/10/2008

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew, Inc.
% Mr. Rishi Sinha
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

MAY - 8 2008

Re: K080625
Trade/Device Name: MIS Hip Stem with Stiktite
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: April 10, 2008
Received: April 11, 2008

Dear Mr. Sinha:

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 Biometric's (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 toll-free number (800) 638-2041 or (240) 276-3150 or the 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

Indications for Use

510(k) Number (if known): K080625 (pg 1/1)

Device Name: MIS Hip Stem with Stiktite

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

Neil R. Ogden for nxn

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K080625