K100481 #1/2

Smith & Nephew, Inc.
Summary of Safety and Effectiveness
MDF Revision Hip System Line Additions

JUL 15 2010

Contact Person and Address
Natalie P. Williams
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Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
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Date of Summary: 07/14/2010

Name of Device: Smith & Nephew MDF Modular Sleeve
Common Name: Modular Sleeve
Device Classification Name and Reference: 21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Device Class: II
Panel Code: Orthopaedics/87 MEH

Device Description
The MDF Revision Hip System is comprised of a stem, modular neck, and modular sleeve component. The components of the revision hip system modularly connect together to form the complete MDF Revision Hip System construct. The Extra Small (XSM) Modular Sleeve line additions mate with similar size femoral stems in the MDF Revision Hip System and lock onto the proximal end of the stem. The XSM Modular Sleeves are manufactured from titanium alloy (Ti-6Al-4V). The XSM MDF Modular Sleeve line additions are grit-blasted and contain a threaded surface with a hydroxylapatite (HA) coating applied by a plasma spray technique.

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; 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 MDF Revision Hip System components are intended for single use only and are to be implanted without bone cement.

Performance Data
Performance testing has been conducted for the subject devices in accordance with the following guidance documents:

- *Non-Clinical Information for Femoral Stem Prostheses,* dated September 2007
- *Draft Guidance Document for Testing Non-Articulating, "Mechanically Locked," Modular Implant Components,* dated May 1995

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- *Calcium Phosphate (Ca-P) Coating Draft Guidance Document for Preparation of FDA Submissions for Orthopaedic and Dental Endosseous Implants*, dated February 1997

Environmental corrosion fatigue, pre-fatigue disassociation, and post-fatigue disassociation have been evaluated. A review of testing has demonstrated that there are no new issues related to the safety or effectiveness of the subject devices.

Substantial Equivalence Information

The overall design of the Smith & Nephew Extra Small MDF Modular Sleeve line additions is substantially equivalent to the modular sleeves that currently exist as part of the MDF Revision Hip System cleared via K081124. The XSM Modular Sleeves utilize an HA coating on a grit blasted surface to achieve cementless fixation and are substantially equivalent to the Synergy Press Fit Stem (K970337) also featuring HA coating on a roughened titanium substrate to achieve cementless fixation. Giving consideration to the device modifications described in the Device Description section, no changes have been made to the overall design philosophy, intended use, and material choices when compared to the predicate devices. Additional design detail is provided in **Table 1** below.

Table 1: Comparison of Subject K100481 Modular Sleeves to Predicate Devices

Device Comparison	**Modular Sleeves Subject of K100481**	**Predicate MDF Modular Sleeves Subject of K081124**	**Predicate Synergy Press Fit Stems Subject of K970337**
	HA on Grit Blast Modular Sleeves	**Stiktite plus HA Coated Modular Sleeves**	**HA on Grit Blast Press Fit Stems**
Size Offering	Sizes 11 – 26/27; XSM	Sizes 11-25; S, M, L	Sizes 9-18
Materials			
Substrate	Ti-6Al-4V per ASTM F1472	Ti-6Al-4V per ASTM F1472	Ti-6Al-4V per ASTM F1472
Roughened Coating	N/A; substrate is grit-blasted to roughen surface.	CPTi per ASTM F67 (StikTite)	N/A; substrate is grit-blasted to roughen surface.
HA Coating	HA Coated per ASTM F1185	HA Coated per ASTM F1185	HA Coated per ASTM F1185

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 15 2010

Smith & Nephew, Inc.
% Ms. Natalie P. Williams
1450 Brooks Road
Memphis, Tenessee 38116

Re: K100481
Trade/Device Name: Smith & Nephew MDF Modular Sleeve
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
Regulatory Class: Class II
Product Code: MEH
Dated: July 8, 2010
Received: July 9, 2010

Dear Ms. Williams:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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): K100481

Device Name: Smith & Nephew MDF Modular Sleeve

Indications for Use:

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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)

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

510(k) Number K100481