

K113789

APR 19 2012

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**Smith & Nephew, Inc.**  
**Summary of Safety and Effectiveness**  
**Modular Proximally Fluted Hip Stem**

**Contact Person and Address**

Natalie P. Williams  
Regulatory Affairs Specialist  
Smith & Nephew, Inc.  
7135 Goodlett Farms Parkway  
Cordova, TN 38016  
(901) 399-5161

**Date of Summary:** 4/12/2012

**Name of Device:** Smith & Nephew Modular Proximally Fluted Hip Stem

**Common Name:** Femoral Hip Prosthesis

**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, LZO

**Device Description**

Subject of this Abbreviated 510(k) premarket notification is the Modular Proximally Fluted Hip Stem. The subject device is a line addition to the MDF Revision Hip System cleared via premarket notification K081124. The Modular Proximally Fluted Hip Stem is a straight, tapered, distally fixed stem with a modular female 12/14 neck taper. The subject device is manufactured from titanium alloy (Ti-6Al-4V) and has a grit-blast finish. The stems will be available in lengths of 240mm and 300mm in sizes 12-27. The subject devices will mate with the cobalt chrome modular necks cleared with the MDF Revision Hip Stems in premarket notification K081124, but are not designed to utilize the modular sleeves included as part of the MDF Revision Hip System.

**Indications for Use**

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.

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

Environmental corrosion fatigue, post-fatigue pull-off, and fatigue strength testing were performed. The range of motion of the subject device was also evaluated. A review of the testing and analysis has demonstrated that there are no new issues related to the safety or effectiveness of the subject devices. Clinical data was not needed to support the safety and effectiveness of the subject devices.

#### Substantial Equivalence Information

The materials, intended use, indications for use, sterilization, and overall design of the Smith & Nephew Modular Proximally Fluted Hip Stems are substantially equivalent to the MDF Revision Hip Stems cleared in premarket notification K081124. 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. A comparison of the Modular Proximally Fluted Hip Stem to the predicate device is provided in Table 1 below.

Table 1: Comparison of the Modular Proximally Fluted Hip Stems to Predicate Device

Design Features	Device Names	
	Subject Smith & Nephew Modular Proximally Fluted Hip Stem	Smith & Nephew MDF Revision Hip Stem (K081124)
Similar Indications for Use/Intended Use	Yes	Yes
Size Offering	12-27	11-25
Stem Lengths (mm)	240mm; 300mm	240mm; 300mm
Stem Material	Ti-6AL-4V	Ti-6AL-4V
Fluted Tapered Stem	Yes	Yes
Modular Sleeves	No	Yes
Neck Taper	12/14	12/14
Cobalt Chrome Modular Necks	Yes	Yes

#### Conclusion

This Abbreviated 510(k) Premarket Notification is being submitted to request clearance for the Modular Proximally Fluted Hip Stems. Based on the similarities to the predicate device, the devices are substantially equivalent to femoral stem components currently marketed under K081124.



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

Smith & Nephew, Incorporated  
% Ms. Natalie P. Williams  
Senior Regulatory Affairs Specialist  
7135 Goodlett Farms Parkway  
Cordova, Tennessee 38016

APR 19 2012

Re: K113789

Trade/Device Name: Smith & Nephew Modular Proximally Fluted Hip Stem

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, LZO

Dated: April 12, 2012

Received: April 13, 2012

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

K113789

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Indications for Use

510(k) Number (if known):

Device Name: Smith & Nephew Modular Proximally Fluted Hip Stem

Indications for Use:

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.

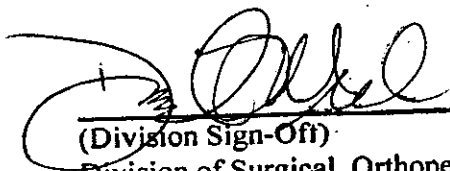
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Smith & Nephew MDF Revision Hip System components are intended for single use only and are to be implanted without bone cement.

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)

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