



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

September 3, 2015

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

Re: K151902

Trade/Device Name: REDAPT™ Revision Femoral System

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: LZO, MEH

Dated: July 8, 2015

Received: July 10, 2015

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**Premarket Notification
Indications for Use Statement**

510(k) Number (if known): K151902

Device Name: Smith & Nephew REDAPT™ Revision Femoral 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 REDAPT™ Revision Hip System components are intended for single use only and are to be implanted without bone cement.

Prescription Use X
(Part 21 CFR 801 Subpart D)

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)



Submitted by: Smith & Nephew, Inc.
Advanced Surgical Devices
1450 East Brooks Road
Memphis, Tennessee 38116

Date of Summary: July 8, 2015

Contact Person and Address: Natalie P. Williams
Sr. Regulatory Affairs Specialist
T: 901-399-5161
F: 901- 566-7081

Name of Device: Smith & Nephew, Inc. REDAPT™ Revision Femoral System

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: Class II

Panel Code: Orthopaedics/87

Product Code: MEH, LZO

Device Description

Subject of this Abbreviated premarket notification is the addition of a new stem design to the Smith & Nephew REDAPT™ Revision Femoral System. The REDAPT Revision Femoral System currently consists of the Modular Proximally Fluted Hip Stems cleared by K113789 and the Modular Sleeved Revision Hip Stems cleared by K121627. The proposed devices are REDAPT Sleeveless Monolithic Revision Stems, new hip stems that will be marketed as part of the REDAPT Revision Femoral System.

The REDAPT Sleeveless Monolithic Revision Stems are a modification of the primary predicate REDAPT Modular Proximally Fluted Hip Stem and reference predicate REDAPT Modular Sleeved Revision Hip Stem. The Sleeveless Monolithic Revision Stem is very similar to the predicate REDAPT hip stems in that it is a tapered, distally fixed femoral stem that is manufactured from forged titanium alloy (Ti-6Al-4V) and has a grit blast finish. The subject device will be available in lengths of 190mm, 240mm, and 300mm and sizes 12-27, in 1mm increments. The REDAPT Sleeveless Monolithic Hip Stems will feature a non-modular, fixed neck with a 12/14 taper.

Intended 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 REDAPT™ Revision Hip System components are intended for single use only and are to be implanted without bone cement.

Technological Characteristics

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

Fatigue strength and range of motion testing have also been evaluated. A review of testing 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 intended use, indications for use, and technological characteristics of the Smith & Nephew REDAPT Sleeveless Monolithic Revision Stems are substantially equivalent to the femoral stems that currently exist as part of the REDAPT Revision Femoral System. A comparison of the subject devices to the predicate devices is provided in Table 5.1 below.

Table 5.1: Comparison of the Sleeveless Monolithic Hip Stems to Predicate Devices

Design Features	REDAPT Sleeveless Monolithic Revision Stems	REDAPT Modular Proximally Fluted Hip Stem (Primary Predicate)	REDAPT Modular Sleeved Revision Hip Stem (Reference Predicate)
510(k) Number	Subject 510(k)	K113789	K121627
Manufacturer	Smith & Nephew, Inc.	Smith & Nephew, Inc.	Smith & Nephew, Inc.
Same Indications for Use/Intended Use?	Yes	Yes	Yes
Size Offering	12-27	12-27	11-27
Stem Lengths (mm)	190mm, 240mm, and 300mm	240mm; 300mm	240mm; 300mm
Stem Material	Ti-6AL-4V	Ti-6AL-4V	Ti-6AL-4V
Fluted Tapered Stem	Yes	Yes	Yes
Grit Blasted Stem	Yes	Yes	Yes
Modular Sleeves Used	No	No	Yes
Neck Taper	12/14	12/14	12/14
Modular Necks Used	No	Yes	Yes
Sterilization	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation
Equivalent Manufacturing Methods	Yes	Yes	Yes

Conclusion

This Abbreviated 510(k) Premarket Notification is being submitted to request clearance for the REDAPT Sleeveless Monolithic Revision Stems. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to above predicate constrained hip systems.