



Food and Drug Administration
10903 New Hampshire Avenue
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Smith & Nephew Incorporated
Mr. Jeff Sprague
Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

November 16, 2015

Re: K150790

Trade/Device Name: REDAPT Porous Acetabular Shell and Cemented Liner

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, JDI, KWZ, LZO

Dated: October 2, 2015

Received: October 5, 2015

Dear Mr. Sprague:

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,

Mark N. Melkerson -S

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

Enclosure

510(k) Summary**Smith & Nephew REDAPT Porous Acetabular Shell and Cemented Liner**

Submitted by:	Smith & Nephew, Inc. Advanced Surgical Devices Division 7135 Goodlett Farms Parkway Cordova, Tennessee 38016
Date of Summary:	November 10 th , 2015
Contact Person	Jeff Sprague, Regulatory Affairs T (901) 399-5215 F (901) 721-2736
Name of Device:	REDAPT Porous Acetabular Shell and Cemented Liner
Common Name:	Total Hip Joint, Acetabular Component
Device Classification Name and Reference:	21 CFR 888.3358 – Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 21 CFR 888.3350 – Hip joint metal/polymer semi-constrained cemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	JDI, KWZ, LZO, LPH

Device Description

The REDAPT Porous Acetabular Shell designed for cementless use is made from titanium alloy (Ti-6Al-4V) powder through an additive manufacturing process. The device design allows for the cementing of cross-linked polyethylene liners into the shell and incorporates screw holes for fixation. The REDAPT Cemented Liner is manufactured from highly cross-linked polyethylene (ASTM F648) via standard machining processes. The liners incorporate integral polyethylene spheres that create a 1.5 mm gap between the porous shell or natural acetabulum for a consistent bone cement mantle.

Intended Use

The REDAPT Porous Acetabular Shell and Cemented Liner are indicated for:

- 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 REDAPT Porous Acetabular Shell is intended for single use only and is to be implanted without bone cement. The REDAPT Cement Liner is intended for single use only and is to be implanted with bone cement.

The above indications are substantially equivalent to the indications cleared for the R3 acetabular shell cleared in K070756.

Technological Characteristics

A review of the mechanical data indicates that the REDAPT Porous Acetabular Shell and Cemented Liner are capable of withstanding expected *in vivo* loading without failure.

Substantial Equivalence Information

The overall design, materials, and indications for use for the REDAPT Porous Acetabular Shell and Cemented Liner are substantially equivalent to the following commercially available predicate devices.

Manufacturer	Description	Submission Number	Clearance Date	Predicate Status
Zimmer Trabecular Metal Technology	Trabecular Metal Acetabular Revision Shells	K050937	5/11/2005	Primary for Porous Shell
Smith & Nephew	REFLECTION 3 Acetabular System	K060630	6/6/2007	Reference for Porous Shell
Smith & Nephew	REFLECTION Acetabular Reinforcement Rings	K962541	9/17/1996	Reference for Porous Shell
Smith & Nephew	REFLECTION Cross-Linked UHMWPE Acetabular Components	K002747	12/15/2000	Primary for Cemented Liner
Smith & Nephew	REFLECTION XLPE Acetabular Liner	K022902	10/2/2002	Reference for Cemented Liner
Smith & Nephew	R3 XLPE Acetabular Liner	K113848	4/24/2012	Reference for Cemented Liner
Smith & Nephew	R3 Acetabular Shell	K070756	6/6/2007	Primary for Indications

The following tests were used as a basis for the determination of substantial equivalence:

- Porous structure characterization
 - Composition
 - Trace element
 - Microstructure
 - Strut shape and size
 - Surface pore diameter
 - Mean void intercept length
 - Porosity
 - Shear mechanical properties
 - Tensile mechanical properties
 - Bending mechanical properties
 - Compressive mechanical properties
 - Abrasion resistance
- Construct fatigue testing
- Acetabular screw testing
- Cemented liner testing
- Biocompatibility
- Range of Motion
- Impaction

Wear performance of the cross-linked polyethylene liners in the subject system was addressed based on a comparison of the minimum thickness in the rim and load bearing regions of the liners with the predicate devices.

All tests which are in relation to the porous structure characterization (physical, chemical or mechanical) are discussed in detail in the Porous Structure Master File **MAF – 2596** and are not included in this 510(k).

Conclusion

As previously noted, this 510(k) Premarket Notification is being submitted to request clearance for the REDAPT Porous Acetabular Shell and Cemented Liner. Based on the similarities to the predicate component and a review of the mechanical testing performed, the devices are substantially equivalent to the commercially available predicate device listed above.