Smith & Nephew Incorporated
Mr. Jeff Sprague
Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

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

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
INDICATIONS FOR USE
Smith & Nephew REDAPT Porous Acetabular Shell and Cemented Liner

510(k) Number (if known): K150790

Device Name: REDAPT Porous Acetabular Shell and Cemented Liner

Indications for 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 Cemented Liner is intended for single use only and is to be implanted with bone cement.

Prescription Use ☒ 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)
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 10th, 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

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.

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