DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 17, 2016

Smith & Nephew, Inc.
Ms. Kim Phan
Regulatory Affairs Specialist
Advanced Surgical Devices Division
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K160923
Trade/Device Name: REDAPT Anteverted Cemented Liner
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JDI, KWZ, LZO
Dated: October 27, 2016
Received: October 28, 2016

Dear Ms. Kim Phan:

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" (21 CFR 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160923

Device Name
REDAPT Anteverted Cemented Liner

Indications for Use *(Describe)*

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary
Smith & Nephew REDAPT Anteverted Cemented Liner

Submitted by:	Smith & Nephew, Inc. Advanced Surgical Devices Division 7135 Goodlett Farms Parkway Cordova, Tennessee 38016
Date of Summary:	October 27th, 2016
Contact Person	Kim Phan, Regulatory Affairs Specialist T: (901) 800-3175 F: (901) 566-7034
Name of Device:	REDAPT Anteverted Cemented Liner
Common Name:	Hip Prosthesis, Acetabular Component
Device Classification Name and Reference:	21 CFR 888.3350 – Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	JDI, KWZ, LZO

Device Description
The REDAPT Anteverted 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 Anteverted 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 Cemented 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 REDAPT Cemented Liners cleared in K150790.

Technological Characteristics
A review of the mechanical data indicates that the REDAPT Anteverted Cemented Liners are capable of withstanding expected *in vivo* loading without failure.

Substantial Equivalence Information
The REDAPT Anteverted Cemented Liners are substantially equivalent to the following commercially available predicate devices by overall design, materials, or indications for use.

Manufacturer	Description	Submission Number	Clearance Date	Predicate Status
Smith & Nephew	REFLECTION Cross-Linked UHMWPE Acetabular Components	K002747	12/15/2000	Primary for Cemented Liner
Smith & Nephew	REDAPT Porous Shell and Cemented Liner	K150790	11/16/2015	Primary for Indications
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

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

- Fatigue
- Push out, Lever Out, and Torque-to-Failure
- Range of Motion
- Impingement

Wear performance of the cross-linked polyethylene liners are substantially equivalent to the REDAPT 0-Degree Liners in K150790 and the REFLECTION Liners in K002747.

Bacterial endotoxin testing was completed and met the acceptable endotoxin limits as stated in the FDA Guidance , "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile," "Pyrogen and Endotoxins Testing: Questions and Answers," and ANSI/AAMI ST72.

Conclusion
As previously noted, this 510(k) Premarket Notification is being submitted to request clearance for the REDAPT Anteverted 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.