510(k) SUMMARY
Smith & Nephew REDAPT Modular Acetabular Shell

Submitted by:	Smith & Nephew, Inc. Advanced Surgical Devices Division 7135 Goodlett Farms Parkway Cordova, Tennessee 38016
Date of Submission:	August 2, 2018
Contact Person:	Meenakshi Gupta, Sr. Regulatory Affairs Specialist T (901) 399-6139 F (901) 721-2748
Name of Device:	REDAPT Modular Acetabular Shell
Common Name:	Total Hip Joint, Acetabular Component
Device Classification Name and Reference:	21 CFR 888.3358 – Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	LPH, MBL
Predicate Device:	REDAPT Porous Acetabular Shell - K150790 R3 Shell Multi-Hole -K092386 REFLECTION Acetabular System-K920430 The predicate devices have not been subject to a design related recall.

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Device Description:

The subject of this Traditional 510(k) is the REDAPT Modular Acetabular Shells. The REDAPT Modular Acetabular Shells are a line extension to the REDAPT Porous Acetabular Shells to allow the un-cemented use of R3 Poly liners. The REDAPT Porous Acetabular Shells were previously cleared for market via premarket notification K150790.

The REDAPT Modular Acetabular Shells are available in same size range as REDAPT Porous Acetabular Shells from 48 mm to 80 mm. The REDAPT Modular Acetabular Shells are made from titanium alloy (Ti-6Al-4V) powder through an additive manufacturing process and has identical porous structure as the predicate REDAPT Porous Acetabular Shell. The inner surface of the subject REDAPT Modular Acetabular shell is modified by a machining process to have an identical inner geometry and locking mechanism as the R3 Multi-hole shells to allow the uncemented use of R3 poly liners that are cleared to use with R3 Multi-hole Shell. The R3 Multi-hole Shells are most recently cleared under premarket notification K092386.The R3 XLPE liners were cleared under 510(k) K070756 and K113848 and the R3 Constrained Liners were cleared under K111635, K122139 and K162641.

Intended Use

The REDAPT Modular Acetabular Shells 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

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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 Modular Acetabular Shell is for single use only and is intended for cementless use.

The above indications are substantially equivalent to the indications cleared for the RADAPT Porous acetabular shell cleared under K150790 and R3 Multi-hole Shell Cleared under K092386.

Technological Characteristics

Device comparisons described in this premarket notification demonstrate that the subject device REDAPT Modular Acetabular Shell are substantially equivalent to the below listed legally marketed predicate devices with regard to intended use, indications for use, design, material and performance characteristics.

Substantial Equivalence Information

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

Table: Predicate Devices

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	REDAPT Porous Acetabular Shell	K150790 (Primary)	11/16/2015
Smith & Nephew, Inc.	R3 Shell Multi-Hole	K092386	11/03/2009
Smith & Nephew, Inc.	REFLECTION Acetabular System	K920430	07/21/1992

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Performance Testing

To further support a determination of substantial equivalence, non-clinical bench (mechanical) testing were conducted on the REDAPT Modular Acetabular Shell. A review of the mechanical data and the technical memo, indicates that the REDAPT Modular Acetabular Shells are substantially equivalent to predicate devices listed in theTable above.

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

- Acetabular Shell and Poly Liner Dissociation Testing-Push-in, Push-put, Lever-out and Torque to Failure testing
- Finite Element Analysis
- Fatigue test
- Corrosion
- Biocompatibility

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.

All tests which are in relation to the porous structure characterization (physical, chemical or mechanical) have been cleared in the REDAPT Porous Acetabular shell 510(k) K150790.

Conclusion

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182109

Device Name
REDAPT Modular Acetabular Shells

Indications for Use *(Describe)*
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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 Modular Acetabular Shell is for single use only and is intended for cementless use.

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.

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