DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 19, 2017

Smith & Nephew, Inc.
Dongeun Kim
Regulatory Affairs Specialist I
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K162641
Trade/Device Name: Smith & Nephew, Inc. R3™ Constrained Liner
Regulation Number: 21 CFR 888.3310
Regulation Name: Hip Joint Metal/Polymer Constrained Cemented Or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: KWZ
Dated: May 18, 2017
Received: May 19, 2017

Dear Dongeun Kim:

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,

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)*
K162641

Device Name
Smith & Nephew, Inc. R3™ Constrained Liner

Indications for Use *(Describe)*
The R3™ Constrained Liner Acetabular System is an uncemented prosthesis intended to replace a hip joint. The Constrained Liner is intended for primary or revision patients at high risk for hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intraoperative instability and for whom all other options to constrained acetabular components have been considered. The R3 Constrained Liner is intended for single use only.

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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We are smith&nephew

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 Brooks Road Memphis, Tennessee 38116
Date of Summary:	June 19, 2017
Contact Person and Address:	Dongeun Kim Regulatory Affairs Specialist I T 901-399-1151 F 901-566-7120
Name of Device:	Smith & Nephew, Inc. R3™ Constrained Liner
Common Name:	Acetabular Liner, Constrained
Device Classification Name and Reference:	21 CFR 888.3310 Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	KWZ

Device Description

Subject of this Traditional premarket notification is the addition of new liner sizes to the Smith & Nephew R3™ Constrained Liner Acetabular System. The R3 Constrained Liner Acetabular System currently consists of the R3 Constrained Liner offered in sizes of 52mm to 66/70mm cleared via premarket notification K111635. The proposed devices are additional sizes to the R3 Constrained Liners that were previously cleared. The proposed devices will be offered in sizes of 48mm, 50mm, 72-74mm, and 76-80mm, and will be marketed as part of the R3 Constrained Liner Acetabular System.

The new R3 Constrained Liner sizes are line additions to the primary predicate R3 Constrained Liners cleared via premarket notification K111635. The subject devices are similar to the primary predicate R3 Constrained Liners in that they are a multi-piece acetabular component consisting of a bipolar bearing that articulates with a captured outer polyethylene liner, locking ring, and outer poly support ring. The subject devices and the primary predicate R3 Constrained Liners utilize a tripolar design allowing motion at two interfaces: the femoral head with the bipolar bearing and the bipolar bearing with the outer liner. The subject devices are identical in design to the cleared R3 Constrained Liners, with the exception that they are smaller or larger in overall size. The new R3 Constrained Liner sizes are also similar to the following additional predicates: R3 Constrained Liners (K122139), REFLECTION Constrained Liners (K021803, K033442), R3 XLPE Liners (K113848), and DePuy Self-Centering Hip Prostheses (K033273). The subject devices are also similar to reference predicate Osteonics Constrained Acetabular Inserts (P960047). The subject devices utilize seven components manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE), forged Titanium Alloy (Ti-6Al-4V), and Cobalt Chrome (CoCr).

Intended Use

The R3™ Constrained Liner Acetabular System is an uncemented prosthesis intended to replace a hip joint. The Constrained Liner is intended for primary or revision patients at high risk for hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered. The R3 Constrained Liner is intended for single use only.

Technological Characteristics

Mechanical testing has been conducted for the subject devices to address the attachment loads (push-in, pull-out, shuck-out, and push-out) and dislocation resistance. The range of motion (ROM) has also been evaluated. A review of the testing has demonstrated that there are no new issues related to safety or effectiveness of the subject devices. Clinical data was not needed to support substantial equivalence.

The Limulus Amebocyte Lysate (LAL) test was used to determine the subject devices meets the specified pyrogen limit specification of less than or equal to 20 EU/device.

Substantial Equivalence Information

The intended use, indications for use, and technological characteristics of the subject R3 Constrained Liners are substantially equivalent to the predicate devices. A comparison of the subject devices to the predicate devices are provided in Table 5.1 below.

Table 5.1: Comparison of the Subject R3 Constrained Liner to the Predicate Devices

Design Features	Subject R3 Constrained Liner	R3 Constrained Liner (Primary Predicate)	R3 Constrained Liner (Additional Predicate)	REFLECTION Constrained Liner (Additional Predicate)	R3 XLPE Liner (Additional Predicate)	DePuy Self-Centering Hip Prosthesis (Additional Predicate)	Osteonics Constrained Acetabular Insert (Reference Predicate)
510(k) Number	Subject 510(k)	K111635	K122139	K021803, K033442	K113848	K033273	P960047
Manufacturer	Smith & Nephew, Inc.	Smith & Nephew, Inc.	Smith & Nephew, Inc.	Smith & Nephew, Inc.	Smith & Nephew, Inc.	DePuy Orthopaedics, Inc.	Howmedica Osteonics Corp.
Indications for Use/Intended Use	The R3 Constrained Liner Acetabular System is an uncemented prosthesis intended to replace a hip joint. The Constrained Liner is intended for primary or revision patients at high risk for hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have	The R3 Constrained Liner Acetabular System is a cemented or uncemented prosthesis intended to replace a hip joint. The Constrained Liner is intended for primary or revision patients at high risk for hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular	The R3 Constrained Liner Acetabular System is a cemented or uncemented prosthesis intended to replace a hip joint. The Constrained Liner is intended for primary or revision patients at high risk for hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular	The REFLECTION Constrained Liner Acetabular System is a cemented or uncemented prosthesis intended to replace a hip joint. The Constrained Liner is intended for primary or revision patients at high risk for hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra' operative instability and for whom all other options to constrained	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.	Indications for the UltimaTM Unipolar heads and the Self-CenteringTM Hip Prostheses previously cleared for Hemi-Hip Arthroplasty remain unchanged. Additions to the indications for use include: Self-CenteringTM Hip Prostheses and unipolar femoral heads are also intended to be used for total hip arthroplasty to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components, when used in conjunction with a UHMWPE bearing surface having an inside	The Osteonics Constrained Acetabular Insert is indicated as a component of a total hip prosthesis in primary or revision patients at high risk of hip dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability.

	been considered. The R3 Constrained Liner is intended for single use only.	components have been considered. The R3 Constrained Liner is intended for single use only.	components have been considered. The R3 Constrained Liner is intended for single use only.	acetabular components have been considered.	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.	diameter corresponding to outside diameter of the metallic cup that is utilized. Use in total hip replacement is indicated in the following additional conditions: 1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia 2. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty ,or total hip replacement.	
Size Offering (Outer Diameter)	48mm, 50mm, 72-74mm, and 76-80mm	52mm to 66/70mm	52mm to 66/70mm	46/48mm-70/76mm	22mm-36mm	39mm-57mm	50mm-74mm
Materials	UHMWPE, Ti-6Al-4V, CoCr	UHMWPE, Ti-6Al-4V, CoCr	UHMWPE, Ti-6Al-4V, CoCr	UHMWPE, Ti-6Al-4V, CoCr	XLPE	UHMWPE	UHMWPE, Ti-6Al-4V, CoCr
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	---------	---------

Conclusion

This Traditional 510(k) Premarket Notification is being submitted to request clearance for the new R3 Constrained Liner sizes of 48mm, 50mm, 72mm-74mm, and 76mm-80mm. Based on the similarities to the predicate devices and a review of the mechanical testing performed, the subject devices are substantially equivalent to the above predicate devices.