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510(k) Summary
R3 XLPE Acetabular Liners

Submitted by:	Smith & Nephew, Inc. Advanced Surgical Devices Division 7135 Goodlett Farms Parkway Cordova, Tennessee 38016
Date of Summary:	April 23, 2012
Contact Person and Address:	John Connor, Regulatory Affairs Specialist T (901) 399-5944 F (901) 566-7961
Name of Device:	Smith & Nephew, Inc R3 XLPE Acetabular Liners
Common Name:	Acetabular Liners
Device Classification Name and Reference:	21 CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis 21 CRF 888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	MBL, MEH, LZO, JDI

Device Description
Subject of this Traditional 510(k) premarket notification is a modification to the R3 22-36mm XLPE Acetabular Liners. The liners were originally cleared under K070756. Four vents have been added to the locking detail of the subject liners. The vents have been added to allow for improved fluid egress from behind the locking beads in an effort to minimize the potential for difficulty seating the liners during aggressive impaction.

Technological Characteristics
This 510(k) was prepared in accordance with the Agency's, "Guidance Document for Testing Acetabular Cup Prostheses," dated May 1995. A review of the mechanical data indicates that the R3 22-36mm XLPE Acetabular Liners are capable of withstanding expected *in vivo* loading without failure. The following mechanical testing of the R3 XLPE Liners was performed:

- Push-out Testing
- Torque-to-Failure Testing
- Lever-out Testing
- Fatigue Testing
- Post-Fatigue Push-out Testing

A review of this testing has demonstrated that there are no new issues related to the safety and effectiveness of the subject devices. Clinical data was not needed to support the safety and effectiveness of the subject devices.

Intended Use

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 Reflection 3 Acetabular System is for single use only and is intended for cementless use.

Substantial Equivalence Information

The substantial equivalence of the R3 XLPE Liners is based on its similarities in indications for use, design features, operational principles, and material composition to the predicate devices listed in the table below.

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Reflection 3 Acetabular System	K061253 K070756	5/31/06 6/6/07
Smith & Nephew, Inc.	Reflection XLPE Acetabular Liners	K002747 K071160	12/15/00 10/5/07
Smith & Nephew, Inc.	R3 36mm XLPE Liners	K092386	11/3/09
Smith & Nephew, Inc.	R3 40 and 44mm XLPE Liners	K093363	1/26/10

Conclusion

As previously noted, this Traditional 510(k) Premarket Notification is being submitted to request clearance for the R3 22-36mm XLPE Acetabular Liners. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to above predicate acetabular liners.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Smith & Nephew, Incorporated
% Mr. John Connor
Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

APR 27 2012

Re: K113848
Trade/Device Name: R3 XLPE Acetabular Liners
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: MBL, MEH, LZO, JDI
Dated: April 23, 2012
Received: April 24, 2012

Dear Mr. Connor:

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.

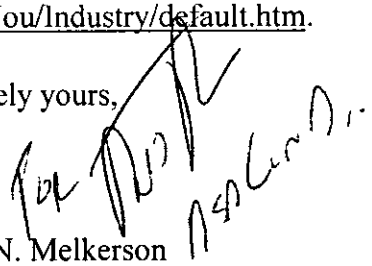
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K113848

Device Name: R3 XLPE Acetabular Liners

Indications for Use:

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Prescription Use __X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113848