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510(K) Summary
Smith & Nephew REFLECTION 3 Acetabular System

SUBMITTER'S NAME:	Smith & Nephew, Inc., Orthopaedic Division
SUBMITTER'S ADDRESS:	1450 East Brooks Road, Memphis, TN 38116
SUBMITTER'S TELEPHONE NUMBER:	901-399-6017
CONTACT PERSON:	Nicholas B. Tabrizi
DATE SUMMARY PREPARED:	February 1, 2007
TRADE OR PROPRIETARY DEVICE NAME:	Smith & Nephew REFLECTION 3
COMMON OR USUAL NAME:	Acetabular Hip Prosthesis
CLASSIFICATION NAME:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, 21 CFR 888.3358
DEVICE CLASS:	Class II
PANEL CODE:	Orthopaedics/87/MBL

A. INTENDED USE:

The REFLECTION 3 Acetabular System is 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, osteonecrosis, avascular necrosis, post 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 diseased and anomalies, and congenital dysplasia; old remote osteomyelitis with and an extended drainage-free period, in which case, the patient should be warned of an above normal danger of infection postoperatively; 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 R3 Acetabular System is for single use only. The R3 Acetabular System is intended for cementless use.

B. DEVICE DESCRIPTION:

The REFLECTION 3 Acetabular System consists of Acetabular shells and liners. The R3 shells are manufactured from titanium alloy. The design of the shells and liners are similar to the REFLECTION 3 Acetabular Shell, the 10MRad REFLECTION 3 Acetabular Liner cleared under K061253 and the DePuy Pinnacle Acetabular Shell cleared under K033273. The REFLECTION 3 liners are manufactured from cross-linked polyethylene. The proposed modifications will include:

- **The addition of Asymmetric Porous Coating to the outside of the R3 Acetabular Shell**
- **The addition of the R3 MAX shell with Asymmetric Porous Coating to the outside of the shell**
- **The addition of the R3 MAX shell with Titanium Bead Porous Coating to the outside of the shell**

The Acetabular shells feature two locking grooves that correspond to locking beads on the XLPE liners, as cleared in K061253. There are also 12 indentions in the face of the shell that mate with

twelve tabs of the XLPE liner to prevent rotation. The R3 Acetabular Shells and the R3 MAX shells will be offered in sizes 40mm-68mm.

C. **SUBSTANTIAL EQUIVALENCE INFORMATION:**

The Smith & Nephew REFLECTION 3 is similar to the following commercially available devices regarding design features, overall indications, and materials:

- Smith & Nephew REFLECTION Acetabular System (K920430, K932755, K990666)
- Smith & Nephew REFLECTION Interfit Shell (K9640094, K990666)
- Smith & Nephew 10MRad REFLECTION Acetabular Liner (K002747)
- Smith & Nephew REFLECTION 3 Acetabular System (K061253)
- DePuy Orthopaedics Inc. Pinnacle Acetabular System (K033273)

D. **SUMMARY OF TECHNOLOGICAL COMPARISON:**

The intended use, design, and materials of the REFLECTION 3 Acetabular System are substantially equivalent to the previously cleared REFLECTION 3 Acetabular System (K061253). Design Control Activities have been completed and the results indicated that the subject device is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew, Inc.
Orthopaedic Division
c/o Nicholas B. Tabrizi
Regulatory Affairs Specialist II
1450 East Brooks Road
Memphis, Tennessee 38116

JUN - 6 2007

Re: K070756
Trade/Device Name: Smith & Nephew REFLECTION 3
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
Dated: May 9, 2007
Received: May 10, 2007

Dear Mr. Tabrizi:

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.

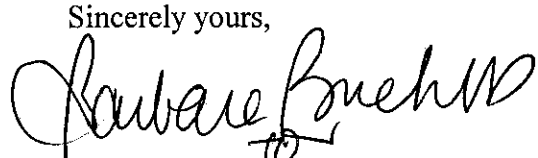
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or on the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070756

Device Name: Smith & Nephew REFLECTION 3 Acetabular System

Indications for Use:

A. Intended Use

The Smith & Nephew REFLECTION 3 is indicated for the following:

- Non-inflammatory degenerative joint disease including osteoarthritis, osteonecrosis, avascular necrosis and post traumatic arthritis;
- Rheumatoid arthritis;
- Slipped capital epiphysis;
- Fused hip;
- Fracture of the pelvis and diastrophic variant;
- Old, remote osteomyelitis with an extended drainage-free period;
- Revision procedures where other treatments have failed; and
- Treatment of proximal femoral non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques;
- Femoral osteotomy;
- Girdlestone resection;
- Fracture dislocation of the hip and;
- Correction of deformity

The REFLECTION 3 Acetabular System is for single use only. The REFLECTION 3 Acetabular System is intended for cementless use.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070756