AUG 2 8 2002

K022576 Page 1 of 1

**Summary of Safety and Effectiveness**
**Smith & Nephew, Inc.**
**Reflection Modified Acetabular Shells**

**Contact Person and Address**

Kim Kelly
Project Manager, Clinical and Regulatory Affairs
Smith & Nephew, Inc., Orthopaedic Division
1450 East Brooks Road
Memphis, TN 38116
(901) 399-6566

**Device Description**

The **Reflection Modified Acetabular Shells** are titanium acetabular components with peripheral fixation holes in the spline of the device. The shells are coated with a -45/+60 porous titanium bead coating. The shells are also offered in a hydroxyapatite coating applied to the porous surface of the implant. The components are designed for use with existing UHMWPE acetabular liners of the Reflection Hip System.

**Device Classification Name**

21 CFR 888.3358 Hip joint metal/polymer/metal, semi-constrained porous coated uncemented prosthesis: Class II

**Indications for Use**

Total 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, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion; femoral neck fracture and trochanteric fractures of the proximal femur with heads involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

The **Reflection Modified Acetabular Shells** are designed for uncemented applications and are single use only.

**Mechanical and Clinical Data**

A review of the mechanical test data indicated that the **Reflection Modified Acetabular Shells** are equivalent to devices currently on the market and capable of withstanding expected *in vivo* loading without failure.

**Substantial Equivalence Information**

The **Reflection Modified Acetabular Shells** shares similarities to currently marketed Smith & Nephew acetabular components in regards to material composition, metallic bead coating, hydroxyapatite coating, shape, locking mechanism, and accessories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2002

Ms. Kim P. Kelly
Project Manager, Clinical and Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 East Brooks Road
Memphis, TN 38116

Re: K022556
Trade/Device Name: Reflection Modified Acetabular Shells
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH, MEH
Dated: July 31, 2002
Received: August 2, 2002

Dear Ms. Kelly:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022556

# Reflection Modified Acetabular Shells
## Indications Statement

Total 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, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion; femoral neck fracture and trochanteric fractures of the proximal femur with heads involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

---

Concurrence of CDRH, Office of Device Evaluation

Prescription Use Yes OR Over-The Counter Use No
(Per 21 CFR 801.109)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022556