K090982

**Summary of Safety and Effectiveness**
**Smith & Nephew Hip Systems with HA**

**Contact Person and Address:**
Gino Rouss, MS
Manager, Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 E. Brooks Road
Memphis, Tennessee 38116
(901) 399-6707

**Date of Summary:** April 19, 2010

APR 21 2010

| | |
|---|---|
| **Name of Device:** | Smith & Nephew Hip Systems with HA |
| **Common Name:** | Hip System |
| **Device Classification:** | CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis – Class II |
| **Device Product Codes:** | MEH, LPH, LWJ, and LZO |

**Device Description**
This 510(k) submission seeks FDA clearance to have the calcium phosphate coating (plasma sprayed from hydroxyapatite (HA) powder) on the subject hip components applied by an alternate coating supplier. The calcium phosphate coating is referred to as "HA coating." The hip system components included in this premarket notification are:

- Porous Synergy Hip Stems
- Non-Porous Synergy Stems
- Porous Anthology Hip Stems
- Porous Reflection Acetabular Shells

The Smith & Nephew Hip Stems with HA coating have been cleared for market by FDA via K052792, K002996 and K970337. The Reflection Acetabular cups with HA coating have been cleared for market by FDA via K990666 and K022556. The design, principle of operation, type of substrate materials, dimensional characteristics and indications for use will not change as a result of the implementation of an alternate HA coating supplier.

**Performance Data**
Summary reports which describe how the applicable guidance documents were used during device development and testing to address risks associated with the subject devices have been reviewed. The subject HA coating underwent characterization per the "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants." All characterization parameters on the starting powders and final coating were provided. In addition, the NIST SRM 2910(a) material was used as a comparator for X-ray diffraction, dissolution rate and solubility product parameters. Prior to being HA coated, the sintered, metallic beaded porous coatings were characterized per "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement." The dual coatings of calcium phosphate coating on the metallic, sintered beaded coatings underwent additional characterization to demonstrate that the definition of porosity was met per 21 CFR 888.3358.

All of the observed results indicate that the Smith & Nephew Hip Systems with HA are substantially equivalent to devices currently cleared for market.

**Intended 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; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Smith & Nephew Hip System components with HA are intended for single use only and are intended to be implanted without bone cement.

**Technological Characteristics**

Although the technological characteristics of the HA coating that will be applied using a plasma spray technique may be considered the same as the predicate HA coating, performance data was provided in support of substantial equivalence. The subject 510(k) includes implant devices that contain HA coating applied to a grit-blasted titanium substrate and a -45/+60 mesh size CpTi porous bead coating.

Clinical data was not needed to support the safety and effectiveness of the subject HA coated devices.

**Substantial Equivalence Information**

The Smith & Nephew Hip Systems with HA are similar in overall design, material and indications to the Smith & Nephew Hip Systems with HA cleared via 510(k) Premarket Notifications K052792, K002996, K970337, K990666, and K022556.

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, Inc.
% Mr. Gino Rouss, M.S.
Manager, Regulatory Affairs
Orthopaedic Division
1450 Brooks Road
Memphis, Tennessee 38116

APR 21 2010

Re: K090982
Trade/Device Name: Smith & Nephew Hip Systems with HA Coating
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: MEH, LPH, LWJ, LZO
Dated: April 19, 2010
Received: April 20, 2010

Dear Mr. Rouss:

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

# Indications for Use

**510(k) Number (if known): K090982**

**Device Name: Smith & Nephew Hip Systems with HA**

**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; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Smith & Nephew Hip System components with HA are intended for single use only and are intended to be implanted without bone cement.

| | | | | |
|---|---|---|---|---|
| Prescription Use | X | AND/OR | Over-The-Counter Use | |
| (Part 21 CFR 801 Subpart D) | | | (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 Surgical, Orthopedic,
and Restorative Devices



510(k) Number K090982