JUL 12 2006

510(k) Summary
Smith & Nephew Patient Matched Hip Stem (PMHS)

Submitter's Name:	Smith & Nephew, Inc., Orthopaedic Division
Submitter's Address:	1450 Brooks Road, Memphis, TN 38116
Submitter's Telephone Number:	901-399-5042
Contact Person:	Laurie Jordan
Date Summary Prepared:	November 16, 2005
Trade or Proprietary Device Name:	Patient Matched Hip Stem
Common or Usual Name:	Hip Stem
Classification Name:	21 CFR 888.3353, Hip Joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis 21 CFR 888.3310, Hip Joint metal/polymer constrained cemented or uncemented prosthesis 21 CFR 888.3360, Hip Joint femoral (hemi-hip) metallic cemented or uncemented prosthesis 21 CFR 888.3390 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87/LZO, MEH, KWL, KWZ, KWY

Device Description

The **Patient Matched Hip Stem**, hereafter referred to as the **PMHS,** is an anatomic style stem that has been developed to match the hip anatomy of a particular patient. The hip stem geometry is derived by allowing the surgeon to shape the implant based on an x-ray of the patient's anatomy.

Intended Use

The Smith & Nephew Patient Matched Hip Stem 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, 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; old, remote osteomyelitis with 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 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 acetabular components have been considered.

The Endoprostheses System is indicated for non-inflammatory degenerative joint disease including osteoarthritis, osteonecrosis, avascular necrosis and post traumatic arthritis; rheumatoid arthritis; arthritis secondary to a variety of diseases and anomalies and correction of functional deformity such as congenital hip dysplasia or ankylosing spondylitis; 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.

The Patient Matched Hip Stem is for uncemented, single use only.

Substantial Equivalence

The intended use, design, and materials of the Smith & Nephew Patient Matched Hip Stem are substantially equivalent to the Smith & Nephew Synergy Global Taper Hip System (K963509), the Smith & Nephew ANTHOLOGY Hip Stem (K052792), and the Biomet Patient Matched Implants (K923452).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2006

Mr. John Reabe
Director, Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 E. Brooks Road
Memphis, Tennessee 38116

Re: K053246
Trade/Device Name: Patient Matched Hip Stem
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 Codes: LZO, KWL, KWY, KWZ, MEH
Dated: May 9, 2006
Received: May 11, 2006

Dear Mr. Reabe:

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 its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson, M.S.
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): K053246

Device Name: Smith & Nephew Patient Matched Hip Stem (PMHS)

Indications for Use:

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Barbara Bruch MD DN MX W

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

510(k) Number K053246

Prescription Use X (Part 21 CFR 801 Subpart D) 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)

Barbara Buchman

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

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