

510(k) Summary
Synergy Hip System

JUL 14 2006

Submitter's Name:	Smith & Nephew, Inc., Orthopaedics
Submitter's Address:	1450 Brooks Road, Memphis, TN 38116
Submitter's Telephone Number:	901-399-6670
Contact Person:	John Reabe
Date Summary Prepared:	April 7, 2006
Trade or Proprietary Device Name:	Synergy Hip System
Common or Usual Name:	Hip joint prosthesis
	Classification Name:
	21 CFR 888.3350, Hip Joint metal/polymer semi-constrained cemented or uncemented prosthesis
	21 CFR 888.3353, Hip Joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
	21 CFR 888.3358, Hip Joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
	21 CFR 787.4300, Implantable Clip
Device Class:	Class II
Panel Code:	Orthopaedics/87/LPH, MEH, JDI, LZO General and Plastic Surgery/79/NEU, FZP

Device Description

The Synergy Hip System includes Synergy Hip System Femoral Components with tantalum markers and acetabular component liners with tantalum markers. The addition of tantalum markers is the only change between the predicate devices and the devices included in this submission. The tantalum markers will allow the surgeon to perform radiostereometric analysis to measure implant migration or movement through radiographs.

Intended Use

The Synergy Hip 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, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

The Synergy Hip System is 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 Synergy Hip System is intended for single use only.

Substantial Equivalence

The intended use, design, and materials of the Synergy Hip System are substantially equivalent to the Smith & Nephew Synergy Global Taper Hip System (K963509, K970337, K991485 and K002996), Smith & Nephew Reflection Cross-Linked UHMWPE Acetabular Component (K002747), Biomet Tantalum Bead, Radiographic Marker (K010348) and Encore Orthopedics Radiographic Marker (K011856).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2006

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

Re: K061066
Trade/Device Name: Synergy Hip System
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: LZ0, LPH, JDI, MEH, NEU, FZP
Dated: June 22, 2006
Received: June 23, 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): K061066

Device Name: Synergy Hip System

Indications for Use:

The Synergy Hip 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, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

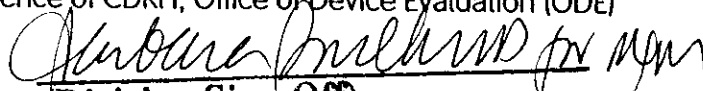
The Synergy Hip System is also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; old, remote osteomyelitis with an extended drainage-free period, in which case, the patient should 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 Synergy Hip System is intended for single use only.

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 General, Restorative,
and Neurological Devices**

510(k) Number K061066