

3/12/99

K990369

510(k) Summary

Submitter's name: Smith & Nephew, Inc.
Submitter's address: 1450 Brooks Road, Memphis, TN 38116
Submitter's telephone number: 901-399-5363
Contact person: Neal Defibaugh
Date summary prepared: February 23, 1999
Trade or proprietary device name: Synergy Cemented Hip Stems
Common or usual name: Prosthetic Hip Joint - Nonporous Tapered Hip Stem

Classification name: 21 CFR 888.3350 hip joint metal/polymer/metal semi-constrained cemented prosthesis-Class II, 87JDI

Substantially Equivalent Legally Marketed Devices

- Global Taper "Tapered" Hip Stem - Smith & Nephew
- Zimmer Versys® Hip Stem - Zimmer
- Wright Perfecta IMC™ Hip Stem - Wright Medical
- Spectron Extra Small Straight Femoral Component - Smith & Nephew
- DePuy AML® Hip Stem - DePuy

Device Description

The Synergy Cemented Hip Stems are manufactured from forged cobalt chrome (CoCr) material (ASTM F799) and are designed for use with existing cobalt chrome or ceramic modular femoral heads with a 12/14 taper.

Device Intended Use

Total hip components are indicated cemented use only in 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 head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

The Synergy Cemented Hip Stems are designed for single use only.

Technological characteristics:

The Synergy Cemented Hip Stems are similar to the legally marketed devices listed above. All of these devices are indicated for total hip replacement, are similar in design to the Synergy Cemented Hip Stems and have the same technological characteristics.

Performance characteristics:

Data indicate that the Synergy Cemented Hip Stems are substantially equivalent to legally marketed devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 12 1999

Mr. Neal Defibaugh
Manager, Clinical/Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, Tennessee 38116

Re: K990369
Trade Name: Synergy Cemented Hip Stems
Regulatory Class: II
Product Code: JDI
Dated: February 5, 1999
Received: February 8, 1999

Dear Mr. Defibaugh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

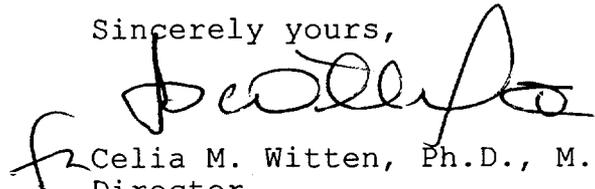
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Neal Defibaugh

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


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

Enclosure

Indications Statement
Synergy Cemented Hip Stems

k990369

Total hip components are indicated for cemented use only in 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 head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

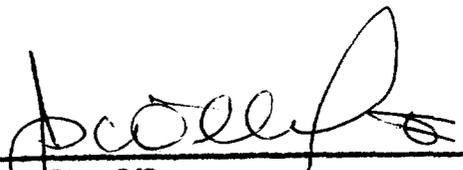
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____

k990369