

JUN 11 2002

K021673

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**Summary of Safety and Effectiveness  
Smith & Nephew, Inc.  
Total Hip Femoral Heads, 12/14 taper**

**Contact Person and Address**

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

**Device Description**

The **Total Hip 12/14 Taper Femoral Heads** are designed for use with both titanium and cobalt chromium alloy femoral components with a 12/14 taper.

**Device Classification Name**

21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous 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 **Total Hip 12/14 Taper Femoral Heads** are designed for single use only.

**Mechanical and Clinical Data**

A review of the mechanical test data indicated that the **Total Hip 12/14 Taper Femoral Heads** are equivalent to devices currently on the market and capable of withstanding expected *in vivo* loading without failure.

**Substantial Equivalence Information**

The **Total Hip 12/14 Taper Femoral Heads** are similar to the femoral heads currently distributed by Smith & Nephew, Inc. All heads are indicated for total hip replacement and are similar to Smith & Nephew CoCr alloy and yttria-stabilized zirconia femoral heads.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Kim P. Kelly, MS  
Senior Regulatory & Clinical Affairs Specialist  
Orthopaedic Division  
Smith & Nephew, Inc.  
1450 East Brooks Road  
Memphis, TN 38116

Re: K021673

Trade/Device Name: Total Hip Femoral Head – 12/14 Taper

Regulation Number: 21 CFR 888.3353

Regulation Name: Hip joint metal/ceramic/polymer semi-constrained  
cemented or nonporous uncemented prosthesis

Regulatory Class: II

Product Code: LZO

Dated: May 20, 2002

Received: May 21, 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.

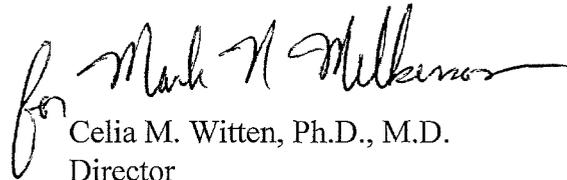
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

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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" (21 CFR 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 H. Milkman

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

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**Total Hip Femoral Heads, 12/14 taper  
Indications Statement**

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Concurrence of CDRH, Office of Device Evaluation

Prescription Use  X

OR  
(Per 21 CFR 801.109)

Over-The Counter Use \_\_\_\_\_

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

510(k) Number  K021673