Summary of Safety and Effectiveness

K971414

Zirconia Ceramic Femoral Heads

JUL 16 [illegible]

DEVICE DESCRIPTION:

These zirconia ceramic femoral heads are compatible with the new 12/14 taper interface of the Revision Hip and Tapered Hip Systems and the Spectron and Cobra stems. They are available with neck lengths of +0 to +8, and with outer diameters of 22 - 28 mm. The femoral heads are manufactured from Yttria stabilized tetragonal Zirconia (YTZP).

INTENDED USE:

The Zirconia femoral head components are to be used with other total hip components as part of a total hip arthroplasty. The components are indicated for cemented and uncemented use for individuals undergoing primary and revision surgery where other treatments or devices have failed for rehabilitating hips damaged as a result of trauma, or non-inflammatory 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.

Indications also include 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 heads involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

The devices are for single use. These head devices may be used with stems that are available with cementless or cement fixation.

Contact Person and Address:

JoAnn Kuhne
Manager, Regulatory and Clinical Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 East Brooks Road
Memphis, TN 38116

Telephone number (901) 396-2121

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. JoAnn Kuhne
Manager, Regulatory and Clinical Affairs
Smith and Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

JUL 16 1997

Re: K971414
Zirconia Ceramic 12/14 Global
Taper (GT) Femoral Heads
Regulatory Class: II
Product Code: LZO
Dated: April 15, 1997
Received: April 16, 1997

Dear Ms. Kuhne:

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 and the following limitation that the package insert must reflect that the Zirconia Ceramic 12/14 Global Taper (GT) Femoral Heads are to be used only with cobalt-chrome and Ti6Al4V alloy hip stems with the 5°43' Morse taper trunnions.

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.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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,

for 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

Exhibit 2

Indications for Use:

INTENDED USE:

The Zirconia femoral head components are to be used with other total hip components as part of a total hip arthroplasty. The components are indicated for cemented and uncemented use for individuals undergoing primary and revision surgery where other treatments or devices have failed for rehabilitating hips damaged as a result of trauma, or non-inflammatory 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.

Indications also include 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 heads involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

The devices are for single use. These head devices may be used with stems that are available with cementless or cement fixation. These heads have not been submitted to the FDA for identical or different intended uses.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971414