

JUL 17 1998

K981847

**510(k) Summary of Safety and Effectiveness
BioloX Alumina Ceramic Femoral Head**

Submitter's name: Smith & Nephew, Inc
Submitter's address: 1450 Brooks Road, Memphis, TN 38116
Submitter's telephone number: 901/396-2121
Contact person: JoAnn Kuhne
Date summary prepared: June 11, 1998

Trade or proprietary device name: BioloX Alumina Ceramic Femoral Head
Common or unusual name: Ceramic Femoral Head
Classification name: 21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis Class II

Legally marketed predicate device: BioloX Alumina Ceramic Femoral Head

Subject device description:

The BioloX Alumina Ceramic Femoral Head is manufactured from aluminum oxide, Al_2O_3 and is designed for use with both titanium and cobalt chromium alloy femoral components with a 12/14 taper. The 28 long size will not be marketed in the USA for use with a Co-Cr-Mo taper.

Subject device intended 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 BioloX Alumina Ceramic Femoral Head is designed for single use only.

Technological characteristics:

The BioloX Alumina Ceramic Femoral Head with a 12/14 taper is similar to the devices listed below.

- BioloX Alumina Ceramic Femoral Head - Smith & Nephew
- Zirconia Ceramic Femoral Head - Smith & Nephew
- Alumina C-Taper Ceramic Femoral Head - Osteonics

All of the devices listed above are indicated for total hip replacement and are similar in design to the BioloX Alumina Ceramic Femoral Head. The new device has the same technological characteristics as the predicate device.

Performance characteristics:

Mechanical testing was performed according to the requirements in the ceramic femoral head draft guidance document. All of the test results indicate that the BioloX Alumina Ceramic Femoral Head is equivalent to devices currently on the market and capable of withstanding *in vivo* loading without failure.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 17 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. JoAnn M. Kuhne
Manager, Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K981847
Biolog Alumina Ceramic Femoral Heads
Regulatory Class: II
Product Code: LZO
Dated: May 22, 1998
Received: May 26, 1998

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 Biolog Alumina Ceramic Femoral Heads are to be used only with cobalt-chrome and Ti6Al4V alloy Smith & Nephew hip stems with the 12/14 taper trunnions, and that the 28 mm long sized femoral head is not for use with cobalt-chrome tapers.

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.

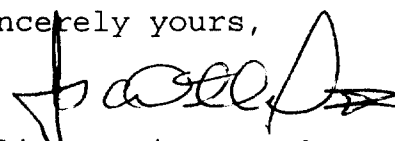
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,



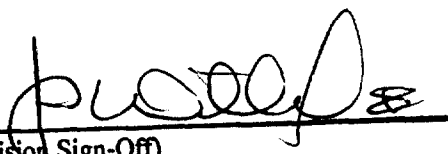
Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement
BioloX Alumina Ceramic Femoral Head

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.

Prescription Use X
(21 CFR 801.109)


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981847