K100412 (1/2)

Summary of Safety and Effectiveness
Biolox Delta Ceramic Femoral Heads
Smith & Nephew, Inc.

Contact Person and Address
Megan Bevill
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, Tennessee 38116
T (901) 399-5340

Date of Summary: April 27, 2010

MAY - 5 2010

Name of Device: Biolox Delta Ceramic Femoral Heads
Common Name: Femoral Heads
Device Classification Name and Reference: 21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Device Class: Class II
Panel Code: Orthopaedics/87 LZO

Device Description
Subject of this Traditional Premarket Notification are Biolox Delta Ceramic Femoral Head line additions. The subject devices are ceramic femoral head components which are intended to be used in conjunction with existing Smith & Nephew 12/14 taper hip stems, and they are intended to articulate against appropriately sized, existing XLPE acetabular liners. The Biolox Delta Ceramic Femoral Heads are manufactured from Biolox delta ceramic material and will be offered in sizes 40 and44mm with offsets of 0, +4, and +8mm.

Biolox Delta Ceramic Femoral Heads in smaller sizes (28, 32, and 36mm) have previously been cleared for market via premarket notification K083762. The only difference between the subject Biolox Delta Ceramic Femoral Heads and those cleared via K083762 is the size offering: the subject devices are offered with a larger diameter than the predicate devices. All other design features, including material choice, taper design, and articular surface finish, are identical. Additionally, Biolox Delta Ceramic Femoral Heads in the same size range have previously been cleared for market via K082844.

Intended Use
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 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.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; 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.

K100412 (2/2)

Summary of Safety and Effectiveness
Biolox Delta Ceramic Femoral Heads
Smith & Nephew, Inc.

Performance Data

Performance testing has been conducted for the subject devices in accordance with the guidance titled "Draft Guidance Document for Testing Non-articulating, 'Mechanically Locked,' Modular Implant Components," dated May 1, 1995, "Guidance Document for Testing Acetabular Cup Prostheses," dated May 1995, and "Draft Guidance for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems", dated January 10, 1995. Range of motion, femoral head burst, femoral head fatigue, wear performance, assembly/disassembly strength, and head/stem construct fatigue have been evaluated. A review of the testing has demonstrated that there are no new issues related to the safety or effectiveness of the subject devices.

Clinical data was not needed to support the safety and effectiveness of the subject device.

Substantial Equivalence Information

The subject Biolox Delta Ceramic Femoral Heads are substantially equivalent to the predicate devices listed in the table below. Giving consideration to the device modifications described in the Device Description section, no changes have been made to the overall design philosophy, intended use, and material choices when compared to the predicate femoral heads.

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Biolox Delta Ceramic Femoral Heads	K083762	3/11/09
Zimmer, Inc.	Biolox Delta Ceramic Femoral Heads	K071535	11/19/07
Encore Medical, LP	Biolox Delta Ceramic Femoral Heads	K082844	11/25/08

Conclusion

As previously noted, this Traditional 510(k) Premarket Notification is being submitted to request clearance for the Biolox Delta Ceramic Femoral Heads. Based on the similarities to the predicate devices and a review of the testing, the devices are substantially equivalent to femoral head components currently marketed under K083762, K071535, and K082844.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Smith & Nephew, Inc.
% Ms. Megan Bevill
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

MAY - 5 2010

Re: K100412
Trade/Device Name: Biolox Delta Ceramic Femoral Heads
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: February 11, 2010
Received: February 16, 2010

Dear Ms. Bevill:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Brennan for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100412

Device Name: Biolox Delta Ceramic Femoral Heads

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 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.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; 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.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100412