



MAY 01 2013

P.O. Box 708  
Warsaw, IN 46581-0708  
574 267-6131

510(k) Summary of Safety and Effectiveness

**Sponsor:** Zimmer GmbH  
Sulzer Allee 8  
Winterthur, CH-8404, Switzerland

**Contact Person:** Rebecca M. Brooks  
Sr. Specialist, Regulatory Affairs  
Telephone: (574) 371-8033  
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**Date:** April 30, 2013

**Trade Name:** BIOLOX *delta* Ceramic Femoral Heads

**Common Name:** Ceramic Femoral Head Prosthesis

**Product Code / Device:** LZO - Prosthesis, Hip, Semi-Constrained,  
Metal/Ceramic/Polymer, Cemented or Non-Porous,  
Uncemented

**Regulation Number / Description:** 21 CFR § 888.3353 – Hip joint metal/ceramic/  
polymer semi-constrained cemented or nonporous  
uncemented prosthesis

**Predicate Device:** BIOLOX *delta* Ceramic Femoral Heads,  
manufactured by Zimmer GmbH, K071535, cleared  
November 19, 2007  
  
Avenir Müller Stem, manufactured by Zimmer  
GmbH, K123392, cleared March 4, 2013  
  
Zimmer *Porolock* MIS Stem, manufactured by  
Zimmer GmbH, K071723, cleared March 7, 2008

**Device Description:** The BIOLOX *delta* Ceramic Femoral Heads are  
fabricated from an alumina matrix composite and  
are available in diameters of 28, 32, 36, and 40 mm  
with a range of offsets to accommodate various  
patient anatomies. They serve as an alternative to  
both metal and alumina ceramic femoral heads for  
use in total hip arthroplasty.

**Intended Use:**

The BIOLOX *delta* Ceramic Femoral Heads are modular components used in total hip arthroplasty and indicated for the following:

Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.

**Comparison to Predicate Device:**

No changes are being made to the designs of the subject BIOLOX *delta* Ceramic Femoral Heads. The proposed modification is limited to expanding the scope of compatible femoral stems. The BIOLOX *delta* Ceramic Femoral Heads are sterilized using equivalent materials and processes as their predicates. The subject devices also have the same intended use and performance characteristics as their predicates.

**Performance Data (Nonclinical and/or Clinical):**

**Non-Clinical Performance and Conclusions:**

Non-clinical testing as well as engineering and risk analyses were performed to demonstrate substantial equivalence of the subject femoral heads to the predicate devices. The specific non-clinical testing and analyses completed include pull-off testing and range of motion analyses. Additionally, a fatigue strength analysis was completed to ensure the new combination does not present a new worst case compared to other legally marketed combinations. This information and testing results formed the basis for a determination of substantial equivalence.

**Clinical Performance and Conclusions:**

Clinical data and conclusions were not needed for this device.



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

May 1, 2013

Zimmer GmbH  
% Zimmer, Incorporated  
Ms. Rebecca M. Brooks  
Senior Specialist, Regulatory Affairs  
P.O. Box 708  
Warsaw, Indiana 46581

Re: K130899

Trade/Device Name: BIOLOX<sup>®</sup> 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: Class II  
Product Code: LZO  
Dated: March 29, 2013  
Received: April 1, 2013

Dear Ms. Brooks:

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 contact 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>. 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,

**Erin D. Keith**

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

Enclosure

## Indications for Use

510(k) Number (if known): K130899 (pg 1/1)

**Device Name:**

BIOLOX<sup>®</sup> *delta* Ceramic Femoral Heads

**Indications for Use:**

The BIOLOX *delta* Ceramic Femoral Heads are modular components used in total hip arthroplasty and indicated for the following:

Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth M Frank -S

Division of Orthopedic Devices

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