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**B. 510(k) SUMMARY (as required by 21 CFR 807.92)****BIOLOX® *delta* Ceramic Femoral Head**

NOV 20 2008

October 6, 2008

**COMPANY:** Aesculap Implant Systems, Inc.  
3773 Corporate Parkway  
Center Valley, PA 18034  
Establishment Registration Number: 3005673311

**CONTACT:** Kathy A. Racosky  
610-984-9291 (phone)  
610-791-6882 (fax)  
[kathy.racosky@aesculap.com](mailto:kathy.racosky@aesculap.com) (email)

**TRADE NAME:** BIOLOX® *delta* Ceramic Femoral Head

**COMMON NAME:** Ceramic Femoral Head

**CLASSIFICATION NAME:** Hip joint Metal/Ceramic/Polymer Semi-Constrained Cemented or Non-Porous Uncemented Prosthesis  
Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented  
Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calcium-Phosphate  
Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented

**REGULATION NUMBER:** 888.3353, 888.3360, 888.3353, 888.3390

**PRODUCT CODE:** LZO, LWJ, MEH, KWY

**SUBSTANTIAL EQUIVALENCE**

Aesculap Implant Systems, Inc. believes that the BIOLOX® *delta* Ceramic Femoral Head is a line extension of Aesculap Implant Systems Excia (K042344, K060918, and K062684) - Hip Systems and Metha Short Stem Hip System (K080584) that were previously cleared. It is also substantially equivalent to the Zimmer BIOLOX *delta* Ceramic Femoral Head (K071535).

**DEVICE DESCRIPTION**

The Aesculap Implant Systems BIOLOX® *delta* Ceramic Femoral Heads are manufactured from an alumina matrix composite. The ceramic femoral head is offered in three diameters of 28, 32, and 36 mm with a range of neck lengths. The BIOLOX® *delta* Ceramic head provides the surgeon another option to both the metal and alumina ceramic femoral heads for use in total hip arthroplasty.

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**INDICATIONS FOR USE**

The Excia Hip System is intended to replace a hip joint.

The device is intended for:

- Patients suffering from severe hip 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, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due previous fusion
- Patients with acute femoral neck fractures

The Excia Hip System is available with two femoral stems. One is manufactured from CoCrMo and is intended for cemented fixation. The other femoral stem is for uncemented fixation and manufactured from Ti with Plasmapore with or without  $\mu$ -CaP®.

The Metha® Hip System (uncemented, press-fit fixation) is intended to replace a hip joint.

The device is intended for:

- skeletally mature individuals undergoing primary surgery for total hip replacement
- 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, protrusion acetabuli, or slipped capital femoral epiphysis
- patients suffering from disability due to previous fusion
- patients with acute femoral neck fractures

**TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))**

The Aesculap Implant Systems BIOLOX® *delta* Ceramic Femoral Heads are offered in similar shapes and sizes as the predicate devices. The material used for the Aesculap Implant Systems device is the same as that used to manufacture the predicate devices.

**PERFORMANCE DATA**

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the;

- "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement",
- "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements",
- "Guidance Document for Testing Non-articulating, "Mechanically Locked" Modular Implant Components",
- "Draft Guidance Document for Testing Acetabular Cup Prostheses",
- "Points to Consider for Femoral Stem Prostheses",
- "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems" and
- "Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices" was completed where applicable.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Aesculap Implant Systems, Inc.  
% Ms. Kathy A. Racosky  
Regulatory Affairs Specialist  
3773 Corporate Parkway  
Center Valley, Pennsylvania 18034

**NOV 20 2008**

Re: K082991

Trade/Device Name: BIOLOX<sup>®</sup> DELTA Ceramic Femoral Head  
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, LWJ, MEH, KWY  
Dated: November 7, 2008  
Received: November 10, 2008

Dear Ms. Racosky:

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 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.

Page 2 – Ms. Kathy A. Racosky

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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRI's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

**A. INDICATIONS FOR USE STATEMENT**

510(k) Number: K082991 (pg 1/1)

Device Name: BIOLOX® delta Ceramic Femoral Head  
For use with the Aesculap Implant Systems Excia and Metha Hip System

**Indications for Use:**

The Excia Hip System is intended to replace a hip joint.

The device is intended for:

- Patients suffering from severe hip 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, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due previous fusion
- Patients with acute femoral neck fractures

The Excia Hip System is available with two femoral stems. One is manufactured from CoCrMo and is intended for cemented fixation. The other femoral stem is for uncemented fixation and manufactured from Ti with Plasmapore with or without  $\mu$ -CaP®.

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The device is intended for:

- skeletally mature individuals undergoing primary surgery for total hip replacement
- 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, protrusion acetabuli, or slipped capital femoral epiphysis
- patients suffering from disability due to previous fusion
- patients with acute femoral neck fractures

  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of General, Restorative,  
 and Neurological Devices

510(k) Number K082991

Prescription Use   X   and/or Over-the-Counter Use \_\_\_\_\_  
(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)