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**B. 510(k) SUMMARY (as required by 21 CFR 807.92)**

**Metha® Hip System**

**JAN 15 2009**

November 25, 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 (email)

**TRADE NAME:** Metha®

**COMMON NAME:** Metha® Hip System

**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 Metha® Hip System additions are substantially equivalent to the existing components of the Metha® Hip Systems (K071916 and K080584) and Aesculap Implant Systems, Inc. BIOLOX *delta* Ceramic Femoral Head (K082991).

**DEVICE DESCRIPTION**

The Metha® BIOLOX® *forte* and *delta* ceramic femoral head are available in head diameters of 28, 32, and 36 mm with a range of neck lengths. The BIOLOX® *forte* ceramic heads are manufactured from ceramic (Al<sub>2</sub>O<sub>3</sub>) and conforms to ISO 6474. The BIOLOX® *delta* ceramic heads are manufactured from an alumina matrix composite. The Metha® cementless femoral stem will be offered in an additional size. The Metha® femoral stem has a Plasmapore® µ-Cap coating on the proximal two thirds of the stem and is manufactured from Ti which conforms to ISO 5832.

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**INDICATIONS FOR USE**

**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 Metha® Hip System additional components are offered in similar shapes and sizes as the predicate devices. The material used for the Aesculap Implant Systems devices are 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.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

JAN 15 2009

Re: K083495

Trade/Device Name: Metha® Hip System

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, LWJ, MEH, KWY

Dated: January 2, 2009

Received: January 5, 2009

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

Page 2 – Ms. Kathy A. Racosky

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.

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 CDRH'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 its toll-free number (800) 638-2041 or (240) 276-3150 or at its 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: K083495

Device Name: Metha® Hip System

**Indications for Use:**

**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

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)

(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

510(k) Number                       
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*K083495*