APR 24 2009

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

BIOLOX® OPTION Ceramic Femoral Head System and Metha® XL Heads

February 5, 2009

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: BIOLOX® OPTION Ceramic Femoral Head System and Metha® XL Heads

COMMON NAME: Total 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 BIOLOX® OPTION Ceramic Femoral Head System and Metha XL Heads is a line extension of Aesculap Implant Systems Excia (K042344, K060918, and K062684) and Metha (K071916, K080584, and K082146) Hip Systems and Aesculap Implant Systems, Inc. BIOLOX *delta* Ceramic Femoral Head (K082991). It is also substantially equivalent to the Zimmer BIOLOX® OPTION Ceramic Femoral Head System (K071535).

DEVICE DESCRIPTION

The Aesculap Implant Systems BIOLOX® OPTION Ceramic Femoral Head System consist of a ceramic head manufactured from an alumina matrix composite available in diameters of 28, 32, and 36 mm and a titanium adapter for the femoral stem cone with a range of neck lengths. The BIOLOX® OPTION Ceramic head provides the surgeon another option to both the metal and alumina ceramic femoral heads for use in total hip arthroplasty.

Two Metha® XL Heads are available. The CoCrMo head is offered in two diameters (28mm and 32mm). The BIOLOX® *delta* ceramic head is composed of an alumina matrix composite and is available in two diameters (32mm and 36mm).

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 µ-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

TECHNOLIGICAL CHARACTERISTICS(compared to Predicate(s))

The Aesculap Implant Systems BIOLOX® OPTION Ceramic Femoral Head System and Metha® XL 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 Poletheylene (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

APR 24 2009

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

Re: K090299
Trade/Device Name: Novation Biolox® Option Ceramic Femoral Head and Metha XL 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, LWJ, MEH, KWY
Dated: March 26, 2009
Received: March 27, 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 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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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: K090299 (pg 1/1)

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

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

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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 _____