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K060918

MAY 26 2006

**B. 510(k) SUMMARY (as required by 21 CFR 807.92)****Excia Total Hip System  
(12/14 Trunnion with Ceramic Head)  
April 3, 2006**

**COMPANY:** Aesculap<sup>®</sup>, Inc.  
3773 Corporate Parkway  
Center Valley, PA 18034  
Establishment Registration Number: 2916714

**CONTACT:** Kathy A. Racosky  
800-258-1946 (phone)  
610-791-6882 (fax)  
[kathy.racosky@aesculap.com](mailto:kathy.racosky@aesculap.com) (email)

**TRADE NAME:** Excia Total Hip System 12/14 Trunnion with Ceramic Head

**COMMON NAME:** Femoral Hip Stem and ceramic head

**CLASSIFICATION NAME:** Prosthesis, hip, semi-constrained, metal/polymer, uncemented  
Prosthesis, hip, semi-constrained, metal/polymer, cemented  
Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented

**REGULATION NUMBER:** 888.3360, 888.3350, 888.3353

**PRODUCT CODE:** LWJ, JDI, LZO

**SUBSTANTIAL EQUIVALENCE**

Aesculap<sup>®</sup>, Inc. believes that the 12/14 Trunnion with Ceramic Head is a line extension of Aesculap's Excia Total Hip System that was cleared (K042344). It is also substantially equivalent to the BiContact Hip System (K040191), DePuy Ceramic Femoral Heads (K031803) and Alumina Ceramic Femoral Heads, 28 and 32 MM (K030724).

**DEVICE DESCRIPTION**

The Excia femoral component is available in two designs. One is manufactured from Ti with a plasma spray coating (Plasmapore). This component is intended for uncemented use. The other femoral component is manufactured from CoCrMo and is intended for cemented use. Both femoral components have a 12/14 trunnion.

The ceramic heads are available in head diameters of 28mm, 32mm, and 36mm in three neck lengths each. They are for use only with the Ti alloy cementless stems. The cemented or cementless femoral stems may be used with the CoCrMo head that was cleared in BiContact (K040191). The acetabular insert is UHMWPE and is available

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in a 36mm symmetrical design. The 12/14 femoral component and ceramic head are used in conjunction with Plasmacup (K042344) for total hip arthroplasty.

### **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 a Ti plasma spray.

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

The new components of the Excia Total Hip System are offered in similar shapes and sizes as the predicate devices. The material used for the Aseculap 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 Opposing 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

MAY 26 2006

Aesculap, Inc.  
c/o Ms. Kathy A. Racosky  
Regulatory Affairs Associate  
3773 Corporate Parkway  
Center Valley, Pennsylvania 18034

Re: K060918

Trade/Device Name: Excia Total Hip system 12/14 Trunnion with Ceramic Head  
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, JDI, LWJ  
Dated: May 2, 2006  
Received: May 4, 2006

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

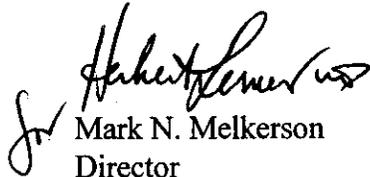
Page 2 – Ms. Kathy Racosky

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.

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson" with a stylized flourish at the end.

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

Enclosure

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**A. INDICATIONS FOR USE STATEMENT**

510(k) Number: K060918

Device Name: **Excia 12/14 Trunnion with Ceramic Head**

**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
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 \_\_\_\_\_  
 (Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K060918

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)