DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 9, 2015

Aesculap Implant Systems, LLC
Ms. Julie Tom Wing
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K150062
Trade/Device Name: Excia Total 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, KWY
Dated: January 12, 2015
Received: January 13, 2015

Dear Ms. Wing:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150062

Device Name
Excia Total Hip System

Indications for Use *(Describe)*
The Excia Hip System is intended to replace a hip joint.

The device is intended for:
• 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 ephiphysis
• Patients suffering from disability due to previous fusion
• Patients with acute femoral neck fractures

The Excia Hip System is available with two (2) femoral stems. One is manufactured from CoCr and intended for cemented fixation. The other femoral stem is for uncemented fixation and manufactured from Ti with Plasmapore with or without μCaP®.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

K150062

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

Excia Total Hip System
Excia T Cemented Femoral Stem

January 12, 2015

COMPANY:
Aesculap Implant Systems, LLC
3773 Corporate Parkway
Center Valley, PA 18034

Establishment Registration Number: 3005673311

CONTACT:
Julie Tom Wing
610-984-9147 (phone)
610-791-6882 (fax)
julie.tomwing@aesculap.com

TRADE NAME:

Excia Total Hip System

COMMON NAME:

Femoral Hip Stem

CLASSIFICATION NAME(s):
Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Hip joint femoral (hemi-hip) metal polymer cemented or uncemented prosthesis

REGULATION NUMBER(S): 888.3353; 888.3360; 888.3390

CLASSIFICATION PRODUCT CODE(S): LZO

SUBSEQUENT PRODUCT CODE(S): LWJ; KWY

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, LLC believes that the addition of cemented Excia T femoral stems to Excia Total Hip System is substantially equivalent to Aesculap Implant Systems Excia Total Hip System (510(K)s K140915 and K060918).

DEVICE DESCRIPTION

Excia T cemented femoral stem is manufactured from CoCrMo. The femoral stem will be offered in a 12/14 taper in stem sizes 10 to 20. The stems are designed without a trochanter wing and features a shorter stem length with an asymmetrical distal tip.

Excia T femoral stem is intended for cemented use.

PURPOSE FOR PREMARKET NOTIFICATION

The purpose of this premarket notification is to gain clearance of Excia T 12/14 cemented femoral stems, a line extension which complements the full product range of offered stems in Aesculap Implant Systems Excia Hip System (510(K)s K140915, K042344, K060437, K060918, and K061344, and K092143).

INDICATIONS FOR USE

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

The device is intended for:

- 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 ephiphysis
- Patients suffering from disability due to previous fusion
- Patients with acute femoral neck fractures

The Excia Hip System is available with two (2) femoral stems. One is manufactured from CoCr and intended for cemented fixation. The other femoral stem is for uncemented fixation and manufactured from Ti with Plasmapore with or without µCaP®.

TECHNOLOGICAL CHARACTERISTICS (compared to Predicate(s))

The addition of 12/14 Excia T cemented femoral hip stems to Aesculap Excia Hip System is substantially equivalent to the Excia Total Hip System. The subject device has the same technological characteristics through comparison of the currently marketed stem indications for use, design, materials of construction, manufacturing process, and range of sizes offered.

PERFORMANCE DATA

Endurance properties of the Excia T cemented stem, head and neck were evaluated in accordance to *Guidance for Industry and FDA Staff Non-clinical Information for Femoral Prostheses, September 17, 2007;* ASTM F2068-09; ISO 7206-4 and ISO 7206-6. Testing demonstrated that the subject device is substantially equivalent to the predicate devices.