K103384

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510(k) Summary

MAR 16 2011

NAME OF SPONSOR:

Ortho Development Corporation
12187 South Business Park Drive
Draper, Utah 84020

510(k) CONTACT:

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Regulatory Affairs Manager
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DATE PREPARED:

November 15, 2010

PROPRIETARY NAME:

Escalade Acetabular Cup System

COMMON NAME:

Acetabular Cup Prosthesis

CLASSIFICATION:

21 CFR 888.3358, Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, Class II device
21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

DEVICE PRODUCT CODE:

LPH, LZO

PREDICATE DEVICES:

TriPlus Acetabular Cup System, *Ortho Development Corp.* (K042565)

Pinnacle Acetabular Cup System, *DePuy Orthopedics, Inc.* (K062148, K000306)

DEVICE DESCRIPTIONS:

The Escalade Acetabular Cup System is a modular system intended for the replacement of the natural articular surface of the hip joint in a total hip replacement surgery. The system consists of acetabular shells, liners, bone screws, apical screw hole cover, and femoral heads.

Acetabular shells are hemispherical in shape and are designed for press-fit, cementless surgical applications. The shells are machined from titanium alloy (Ti-6Al-4V ELI) and are plasma spray coated (Ti-CP) for biological fixation. Escalade liners are manufactured from extensively cross-linked UHMWPE and are available in neutral face and 10° hooded options. Liners are configured for use with femoral head diameters ranging from 26mm to 40mm. The Ø6.5mm cancellous bone screws and the apical screw hole cover are manufactured from titanium alloy (Ti-6Al-4V ELI). The 36mm and 40mm diameter femoral heads made of cobalt chromium alloy (Co-28Cr-6Mo) are being added to the currently offered femoral head sizes in conjunction with this system.

The following marketing claim will be made for Escalade Acetabular Liners:

Ortho Development Corp Escalade™ UHMWPE liners reduce wear by 88% compared to previously cleared TriPlus UHMWPE liners when used with CoCrMo femoral heads. An in-vitro hip simulator study was conducted using the following polyethylene liners: Escalade 36mm ID liners for a 52mm OD shell, Escalade 40mm ID liners for a 56mm OD shell, and TriPlus 32mm ID liners for a 52mm OD shell as a control. The bearing surface thickness was 6.7mm for the Escalade liners and 5.8mm for the TriPlus liners. Test and control liners were manufactured by Ortho Development Corp. The Escalade Liners were made from compression molded GUR 1020 material which was crosslinked, machined, and ETO sterilized prior to the study. TriPlus liners were machined from compression molded GUR 1020 material and sterilized by gamma irradiation in an inert gas package. Test and control liners were tested for 5 million cycles on an AMTI 12 station hip simulator with a standard walking gait cycle as specified by ISO 14242-1 with a 3.0 kN peak load. The femoral head components were CoCrMo heads manufactured by Ortho Development. The lubricant was 94% bovine serum (Sigma-Aldrich) with 10.7mMol EDTA and penicillin-streptomycin solution (Fisher Scientific). The protein concentration of the lubricant was 74 g/L. The steady state wear rates determined from the study were 1.5 ± 0.6 mg/MC for both the 36mm and the 40mm Escalade liners. The steady state wear rate for the TriPlus control liners was 12.8 ±1.6 mg/MC. The average total wear for 5 million cycles was 6.6 mg for the 40mm liners, 6.7 mg for the 36mm liners, and 67.9 mg for the 32mm control liners. Reduced wear claims are based upon the results of in-vitro hip wear simulator tests which have not been shown to quantitatively predict clinical wear performance. Also, a reduction in total polyethylene wear volume or wear rate alone may not result in an improved clinical outcome as wear particle size and morphology are also critical factors in the evaluation of the potential for wear mediated osteolysis and associated aseptic implant loosening. Particle size and morphology were not evaluated as part of this wear claim.

INTENDED USE:

The Escalade Acetabular Cup System is intended for the replacement of the natural articular surface of the hip joint in a total hip replacement surgery. Total hip arthroplasty is intended to provide increased patient mobility and to decrease pain by replacing the damaged hip joint in patients having sufficiently sound bone to support the implants.

INDICATIONS FOR USE:

The Escalade Acetabular Cup System is indicated for use in total hip arthroplasty procedures where the means of cup fixation is uncemented, biological fixation. The Escalade Acetabular Cup System is compatible with the Ovation Hip Stem System (indicated for uncemented, biological fixation of the stem) and the Encompass Hip Stem System (indicated for both cemented and uncemented, biological fixation of the stem).

Total hip arthroplasty is indicated for the following conditions:

1. Notably impaired hip joints due to osteoarthritis, rheumatoid arthritis and/or post traumatic arthritis.
2. Previously failed hip surgery.

3. Fractures of the femoral neck or head.
4. Avascular necrosis of the femoral head.
5. Congenital dysplasia or other structural abnormalities where sufficient bone stock exists to properly seat the prosthesis.

BASIS OF SUBSTANTIAL EQUIVALENCE:

Ortho Development believes that the Escalade Acetabular Cup System is substantially equivalent to the previously cleared predicate devices based on similarities in intended use, design, materials, size range, manufacturing methods, packaging, liner material and mechanical performance.

Testing that supports the substantial equivalence of the devices includes construct wear, liner/shell interconnection strength testing (assembly, push-out, lever-out, torque-out), static and dynamic impingement, range of motion, shell deformation testing, and offset liner rim fatigue testing. In addition, porous plasma spray coating and polyethylene liner material characterization was performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ortho Development Corporation
% Mr. Thomas D. Haueter
Regulatory Affairs Manager
12187 South Business Park Drive
Draper, Utah 84020

MAR 16 2011

Re: K103384
Trade/Device Name: Escalade Acetabular Cup System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO
Dated: March 08, 2011
Received: March 11, 2011

Dear Mr. Haueter:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

for

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

Enclosure

Indication for Use Form
Ortho Development
Escalade 510(k)

510(k) Number: K103384

Device Name: Escalade Acetabular Cup System

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

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for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103384