DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 17, 2016

Ortho Development Corporation
Mr. Drew Weaver
Director of Quality Assurance and Regulatory Affairs
12187 South Business Park Drive
Draper, Utah 84020

Re: K161080
Trade/Device Name: Escalade Legend® Acetabular Shell
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: April 15, 2016
Received: April 18, 2016

Dear Drew Weaver:

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 Parts 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)*
K161080

Device Name
Escalade Legend® Acetabular Shell

Indications for Use *(Describe)*
This device is intended for use in total hip arthroplasty. The device is intended for uncemented, biological fixation only in cases of:

- Notably impaired hip joints due to osteoarthritis, rheumatoid arthritis and/or post traumatic arthritis.
- Previously failed hip surgery.
- Fractures of the femoral neck or head.
- Avascular necrosis of the femoral head.
- Congenital dysplasia or other structural abnormalities where sufficient bone stock exists to properly seat the prosthesis.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5
510(k) Summary

Name of Sponsor:	Ortho Development Corporation 12187 South Business Park Drive Draper, Utah 84020
510(k) Contact:	Drew Weaver Director of Quality Assurance and Regulatory Affairs Telephone: (801) 619-3419 Facsimile: (801) 553-9993 Email: DWeaver@orthodevelopment.com
Date Prepared:	April 15, 2016
Proprietary Name:	Escalade Legend® Acetabular Shell
Common Name:	Acetabular Cup Prosthesis
Classification:	21 CFR 888.3358, Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis Class II device
Device Product Code:	LPH, LZO
Predicate Devices:	Escalade Acetabular Cup System (K103384) Ortho Development Corporation

5.1 Device Description

The proposed subject device Escalade Legend® Acetabular Shell is a line extension to the Escalade Acetabular Cup System (K103384). The Escalade Acetabular Cup System is a modular system intended for the replacement of the natural articular surface of the hip joint in total hip replacement surgery. The system consists of acetabular shells, liners, bone screws, apical screw hole cover, and femoral heads.

The Escalade Legend® Acetabular Shells are hemispherical in shape and are designed for press-fit, cementless, surgical applications. The subject device differs from the shell in K103384 device in the use

of sintered titanium beads instead of titanium plasma spray for bone fixation. Information regarding the sintered titanium beads can be found in MAF-2172, Titanium ASYMMATRIX™ Type 1, Orchid Orthopedic Solutions, Memphis, TN.

The liners, bone screws, apical screw hole cover and femoral heads used have been cleared under K103384 and are not a part of this submission.

A summary of the Intended Use, Indications for Use, Summary of Technological Characteristics, and Testing performed on the subject device as they relate to the unmodified K103384 device can be seen in Table 5.1 below. Only information pertaining to the acetabular shell is included because the liners, bone screws, apical screw hole cover, and femoral heads are not part of this submission.

Table 5.1 - Summary of Escalade Legend Acetabular Shell Characteristics

Escalade Acetabular Shell K103384	Escalade Legend® Acetabular Shell
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.	Same
Indications for Use	
This device is intended for use in total hip arthroplasty. The device is intended for uncemented, biological fixation only in cases of: 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.	Same
Technological Characteristics	
Hemispherical in shape	Same
Machined of Ti-6Al-4V ELI, ASTM F136	Same
Snap fit with EXLPE liner	Same
Uncemented biological bone fixation	Same
No-hole and 3-hole shells offered	Same
Coating material: CP Ti per ASTM F1580	Same
Coating type: Plasma Spray	Coating type: Sintered Bead

Non-Clinical Testing	
Liner connection strength test per ASTM F1820	Same
Coating tests per ASTM F1044, ASTM F1160, ASTM F1854, ASTM F1978	Same

5.2 Clinical Test Summary

No clinical studies were performed.

5.3 Conclusions

Based on the similarities to the predicate device and the unchanged testing performance, Escalade Legend® Acetabular Shell is substantially equivalent to the predicate device that was cleared under K103384.