May 30, 2018

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

Re: K173951
Trade/Device Name: Legend® Acetabular Liners
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 30, 2018
Received: May 1, 2018

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 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173951

Device Name
Legend® Acetabular Liner

Indications for Use *(Describe)*

This device is intended for use in total hip arthroplasty. The device is intended for uncemented, press-fit use 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.

12187 So. Business Park Drive
Draper, Utah 84020
801-553-9991/ fax 553-9993
Orthodevelopment.com

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:	May 24, 2018
Proprietary Name:	Legend® Acetabular Liner
Common Name:	Acetabular Liner 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
Device Class:	Class II device
Device Product Code:	LPH, LZO
Predicate Devices:	K103384 – Acetabular Cup System Ortho Development Corporation

5.1 Device Description

The proposed subject device is a line extension to the acetabular cup system previously cleared in K103384. The predicate 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 subject and predicate acetabular liners are both made of highly cross-linked polyethylene and are hemispherical in shape with positive locking, liner stabilization, and anti-rotation features.

The Legend Acetabular Liners (subject device) differ from the predicate device, cleared in K103384, through the addition of new sizes. Other components of the system have not been modified and are not a part of this submission other than by reference.

5.2 Indications for Use

This device is intended for use in total hip arthroplasty. The device is intended for uncemented, press-fit use 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.

5.3 Basis for Substantial Equivalence:

The Legend Acetabular Liners have the same technological characteristics as the predicate devices. These include:

- Indications for use
- Intended Use
- Fundamental design
- Material
- Manufacturer
- Manufacturing Processes
- Sterilization
- Packaging

The following non-clinical tests were conducted on various configurations of the Legend Acetabular Liners and met the predetermined acceptance criteria:

- Impingement Performance per ASTM F-2582
- Bacterial endotoxin testing using LAL pyrogen testing methodology per ANSI/AAMI ST72:2011

The fundamental scientific technology of the Legend Acetabular Liner is the same as the previously cleared predicate device. The mechanical test results demonstrate that the Legend Acetabular Liners are as safe, as effective, and perform as well as or better than the legally marketed device predicate. No clinical studies were performed.

Based on similarities in intended use, design, manufacturing methods, sterilization, packaging, and the mechanical test results, the Legend Acetabular Liner is substantially equivalent to the predicate device that was cleared under K103384.