October 11, 2024

Ortho Development Corp.
Drew Weaver
Director of Regulatory Affairs
12187 S. Business Park Drive
Draper, Utah 84020

Re: K242833
Trade/Device Name: 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: September 11, 2024
Received: September 19, 2024

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Limin Sun -S

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K242833

Device Name
Legend® Acetabular Shell

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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ORTHO DEVELOPMENT®

510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

Name of the Sponsor:	Ortho Development® Corporation 12187 South Business Park Drive Draper, Utah 84020
510(k) Contact:	Name: Drew Weaver Position: Director of Regulatory Affairs Address: 12187 S. Business Park Drive Draper, UT 84020 USA Telephone: (801) 553-9991 Email: dweaver@orthodevelopment.com
Date Prepared:	October 10, 2024
Submission Type:	Special
Proprietary Name:	Legend® Acetabular Shell
Common Name:	Acetabular Shell
Product Code / Classification:	LPH Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented 21 CFR 888.3358: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Associated Product Code(s) / Classification:	LZO Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented 21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Device Class:	Class 2
Primary Predicate Device:	Ortho Development Escalade Legend® Acetabular Shell (K161080)

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1.0 Device Description:

The Legend® Acetabular Shell is a one-piece, hemispherical shell prostheses, designed for single, uncemented use. Device fixation is achieved via press-fit into a prepared acetabulum, which maximizes contact between the shell and bone.

The Legend® Acetabular Shell is manufactured from titanium alloy Ti-6Al-4V ELI per ASTM F136. The outer surface of the shells are coated with commercially pure titanium (CPTi)(ASTM F1580) sintered porous coating. The inner surface of the shell is designed to lock together with the Escalade® and Legend® Acetabular Liners which are made from extensively cross-linked polyethylene. The Legend® Acetabular Shell is also designed to be used with cancellous bone screws and apical plugs.

The existing Legend® Acetabular Shell (K161080) is coated with commercially pure titanium (CPTi) sintered bead coating. This submission allows a similar sintered coating to be applied by an additional supplier: Avalign Thortex (MAF-2607) in addition to the original supplier.

2.0 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:

• 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.

3.0 Comparison of Technological Characteristics:

The purpose of this 510(k) is to add an additional supplier of commercially pure titanium sintered coating. The K161080 device has the same type of coating but applied by a different supplier.

The subject Legend® Acetabular Shells are identical to the predicate Escalade Legend® Acetabular Shells from K161080 in all other ways.

No other changes are made to this device.

The indication for use/intended use, technological characteristics, basic design, device material, and principles of operation are unchanged.

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The coating from the new supplier was evaluated using well established methods and recognized consensus standards to confirm that it meets the original design inputs of the predicate.

4.0 Performance Data:

The new coating from Avalign Thortex meets the requirements of FDA Guidance: *Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement, April 28, 1994.*

The coating material is commercially pure Titanium per ASTM F1580.

Shear strength >2,900 psi per ASTM F1044.

Tensile Strength >2,900 psi per ASTM F1147

It meets the design specifications listed in 21 CFR 888.3358.

5.0 Other Considerations:

Aside from the additional coating supplier, no other changes to the device have been made. The sterilization, packaging, shelf life, and materials are identical to the predicate. Minor editorial changes have been made to the labeling.

6.0 Substantial Equivalence Conclusion:

Verification and validation has been conducted according to design control procedures within a risk analysis framework to determine that the design outputs meet the design inputs using the same test criteria and methodology as the predicate K161080.

Based on similarities in indication for use/intended use, technological characteristics, basic design, device material, and principle of operation, the Legend® Acetabular Shell is considered substantially equivalent to the previously cleared predicate device.