February 8, 2024

Orchard Medical Development
℅ Justin Gracyalny
Regulatory Affairs Manager
Secure BioMed Evalutations
7828 Hickory Flat Highway, Suite 120
Woodstock, Georgia 30188

Re: K233476
Trade/Device Name: Z1 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, KWY, KWZ, LWJ, MEH
Dated: January 5, 2024
Received: January 5, 2024

Dear Justin Gracyalny :

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.

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, PhD
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K233476

Device Name

Z1 Hip System

Indications for Use *(Describe)*

Z1 Hip System is intended for total or hemi hip arthroplasty and is indicated for the following conditions:
• Advanced wear of the joint due to degenerative, post-traumatic or rheumatic diseases.
• Failed previous hip surgery including joint reconstruction (osteotomy), arthrodesis, hemi-arthroplasty or total hip replacement (THR).
• Acute traumatic fracture of the femoral head or neck.
• Avascular necrosis of the femoral head.

Z1 Hip System is for cementless use only.

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.

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K233476
510(k) SUMMARY:
Orchard Medical Development, LLC Z1 Hip System

Date Prepared	February 7, 2024
Sponsor	Orchard Medical Development, LLC 9450 W. Bryn Mawr Ave, Suite 200 Rosemont, IL 60018 (847) 999-0600
510(k) Contact	Secure BioMed Evaluations Justin Gracyalny, MSE Linda Braddon, Ph.D. 7828 Hickory Flat Highway, Suite 120 Woodstock, GA 30188 770-837-2681 Regulatory@SecureBME.com
Trade Name	Z1 Hip System
Common Name	Hip Prosthesis
Product Code – Device – Regulation Number	• LZO – Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented (21 CFR §888.3353). • MEH – Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calcium Phosphate (21 CFR §888.3353). • KWZ – Prosthesis, Hip, Constrained, Cemented Or Uncemented, Metal/Polymer (21 CFR §888.3310). • KWY – Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented Or Uncemented (21 CFR §888.3390). • LWJ – Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented (21 CFR §888.3360).
Primary Predicate	K182048 / K192189 Zimmer, Inc. Avenir Complete Hip System
Reference Device(s)	K150862 / K160907 / K210581 DePuy Orthopaedics, Inc. Actis DuoFix Hip Prosthesis K120030 Biomet Manufacturing Corp. Taperloc® Complete Size 4mm and XR 123

Device Description	Z1 Hip System consists of femoral hip stems intended for use in total or hemi hip arthroplasty. The stem is designed for cementless implantation into the proximal femur and mates with compatible femoral heads and adapters for use in total or hemi hip arthroplasty through a 12/14 male taper connection. The stems are manufactured from a forged titanium alloy Ti-6Al-4V and have a wedge-shaped design, with a proximal-to-distal taper. Apart from the highly polished femoral neck region, the entire surface of the stem is grit-blasted and sprayed with a Ti-6Al-4V titanium alloy plasma coating followed by a hydroxyapatite (HA) overcoat. Offered in multiple sizes and neck lengths, the stems are available in Standard, High Offset, and Coxa Vara offsets and as collared or collarless stems in each offset to accommodate various patient anatomies. The hip stems are provided sterile and are for single use only. System-specific instrumentation is available to prepare the femur for implantation of the Z1 Hip System femoral stems. The Z1 Hip System is for use only with the Zimmer Biomet femoral heads and adapters, bipolar heads, and acetabular shells and liners identified in the package insert as compatible components.
Indications for Use Statement	Z1 Hip System is intended for total or hemi hip arthroplasty and is indicated for the following conditions: • Advanced wear of the joint due to degenerative, posttraumatic or rheumatic diseases. • Failed previous hip surgery including joint reconstruction (osteotomy), arthrodesis, hemiarthroplasty or total hip replacement (THR). • Acute traumatic fracture of the femoral head or neck. • Avascular necrosis of the femoral head. Z1 Hip System is for cementless use only.

Comparison of Technological Characteristics

Device Characteristic	**Subject Device Orchard Medical Z1 Hip Stem**	**Primary Predicate Device Zimmer, Inc. Avenir Complete Hip System K182048 / K192189**
Intended Use	Total Hip Arthroplasty, Hemi-Hip Arthroplasty	Total Hip Arthroplasty, Hemi-Hip Arthroplasty
Material	Ti-6Al-4V Titanium Alloy with Ti-6Al-4V plasma coating and hydroxyapatite overcoat	Ti-6Al-4V Titanium Alloy with porous CP-Ti coating and hydroxyapatite overcoat
Fixation Method	Cementless press-fit fixation.	Cementless press-fit fixation.
Stem Size	0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12	0, 1, 2, 3, 4, 5, 6, 6.5, 7, 7.5, 8, 8.5, 9
Collar	Collared, Collarless	Collared, Collarless

Device Characteristic	**Subject Device Orchard Medical Z1 Hip Stem**	**Primary Predicate Device Zimmer, Inc. Avenir Complete Hip System K182048 / K192189**
Neck Offsets	Standard Offset High Offset Coxa Vara	Standard Offset High Offset Coxa Vara
Sterilization	Implant: Gamma, SAL 10^{-6} Instruments: Steam, SAL 10^{-6}	Implant: Gamma, SAL 10^{-6} Instruments: Steam, SAL 10^{-6}
Packaging	Dual PETG / Tyvek blister	Dual PETG / Tyvek blister
Single Use Only	Yes	Yes
Prescription Use Only	Yes	Yes

Technological Characteristics

There are no significant technological differences between the subject and predicate device. The subject device uses similar materials, is a similar design, and achieves its intended use in an identical manner as the predicate and both devices are manufactured using subtractive techniques. Minor differences in stem geometry and sizing are addressed via performance testing and similarity to the reference device.

Non-Clinical Performance Testing Summary

All necessary testing has been performed for the Z1 Hip System to assure substantial equivalence to the predicate device and to demonstrate the subject device performs as intended. All testing was performed on worst case implants or test coupons as dictated by the relevant performance standards. The following evaluations were conducted:

- Distal Fatigue Testing per ISO 7206-4
- Proximal Fatigue Testing per ISO 7206-6
- Range of Motion Evaluation per ISO 21535
- HA and Ti-6Al-4V Coating Characterization per ISO 13779, ISO 2360, ASTM F1926, ASTM F1147, ASTM F1044, ASTM F1854, ASTM F1160, ASTM F1978, ISO 13179-1
- Modular Connection and Corrosion Performance Rationale
- MR Compatibility per ASTM F2213, ASTM F2182, ASTM F2119, and RF Heating Modeling
- Sterilization per ISO 11137-2, ISO 17665-1
- Endotoxin per AAMI ST72
- Biocompatibility per ISO 10993-1, ISO 10993-5

Conclusions

Based on the similarities of the intended use/indications for use, technological and functional characteristics, and the results of the non-clinical performance testing, the subject device is substantially equivalent to the legally marketed predicate device.