September 23, 2022

Total Joint Orthopedics, Inc.
% Holly Rhodes
Vice President, Orthopedic Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, District of Columbia 20001

Re: K220483
Trade/Device Name: Platform® Acetabular 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, LPH, MBL, OQG
Dated: July 25, 2022
Received: July 25, 2022

Dear Holly Rhodes:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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, 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)*

K220483

Device Name
Platform® Acetabular System

Indications for Use *(Describe)*

The Klassic HD Hip System is intended for prosthetic replacement without bone cement in treatment of the following:
• Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis, osteoarthritis, ankylosis, protrusio acetabuli and painful hip dysplasia.
• Patient conditions of inflammatory joint disease (IJD): rheumatoid arthritis.
• Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
• Revision of a previously failed hip arthroplasty.
• Patients who require a total hip replacement.

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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510(k) Summary

Manufacturer: Total Joint Orthopedics, Inc.
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Salt Lake City, UT 84106
Phone: 801.486.6070
Fax: 801.486.6117

Contact: Mr. Chris Weaber
Director of Research and Development

Prepared By: MCRA, LLC
803 7th Street NW
Washington, DC 20001
Phone: 202.552.5800
Fax: 202.552.5798

Date Prepared: September 21, 2022

Device Trade Name: Platform® Acetabular System

Common Name: Acetabular Shell, Acetabular Inserts

Classifications: 21 CFR 888.3353 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

21 CFR 888.3358 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Class II

Product Codes: LZO, LPH, MBL, OQG

Indications for Use:
The Klassic HD® Hip System is intended for prosthetic replacement without bone cement in treatment of the following:

- Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis, osteoarthritis, ankylosis, protrusio acetabuli and painful hip dysplasia.
- Patient conditions of inflammatory joint disease (IJD): rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- Revision of a previously failed hip arthroplasty.
- Patients who require a total hip replacement.

Device Description:
The Klassic HD Hip System employs prostheses designed to help surgeons restore hip joint biomechanics. The purpose of this 510(k) is to add the Platform Acetabular System consisting of the Platform Acetabular Shell with Ti-Coat and Platform Acetabular Inserts with E-Link (Neutral and Hooded) to the Klassic HD Hip System. The Platform Acetabular Shells are fabricated from Ti6Al4V per ASTM F136 and the Platform Acetabular Inserts with E-Link are made from Vitamin E, UHMWPE material. The subject acetabular components are available in various sizes ranging in outer diameters of 44mm to 64mm to match patient anatomy and are compatible with 28mm, 32mm, and 36mm heads. The subject components are provided sterile, for single use, by prescription only.

Predicate Devices:
The modified Klassic HD Hip System is substantially equivalent to the predicate Klassic HD® Hip System (Primary predicate: K100445; Additional predicates: K141972, K173104, K180929) with respect to indications, design, material and function. The information summarized in this 510(k) demonstrates that the subject device is substantially equivalent to the identified predicate devices.

Comparison of Technological Characteristics:
The subject devices feature the same material (Ti6Al4V per ASTM F136 and Vitamin E UHMWPE), same use as acetabular shells and liners, same articular interface design, same compatibility, and same sterilization as predicate shells and liners (K100445).

Discussion of Non-Clinical Testing/ Performance Data:
The subject device underwent push out testing, lever out testing, axial torque disassembly testing, impingement testing, acetabular shell fatigue testing, and deformation testing. In addition, engineering analysis was performed to evaluate material wear and range of motion for the subject devices. Additionally, the Klassic HD® Hip System is in compliance with LAL testing requirements for orthopedic implants.

Non-clinical testing and engineering analysis conducted to demonstrate substantial equivalence was as follows:

- Material wear (via engineering analysis) of acetabular shells and liners
- Range of motion (via engineering analysis)
- Push out testing per ASTM F1820-13
- Lever out testing per ASTM F1820-13
- Axial Torque Disassembly Testing per ASTM F1820-13
- Impingement Testing per ASTM F2582-20
- Acetabular Shell Fatigue Testing per ASTM F3090-20
- Deformation Testing per ISO 7206-12

Conclusion
Testing and engineering analyses demonstrated that the subject acetabular components perform as safe and effective compared to the predicate components and are substantially equivalent to the predicate.