September 8, 2023

Total Joint Othopedics, Inc.
℅ Hollace Rhodes
VP, Orthopedic Regulatory Affairs
MCRA, LLC
803 7th Steet NW
Floor 3
Washington, District of Columbia 20001

Re: K232414
Trade/Device Name: Klassic® Tibial Insert, PS-Post, Klassic All Poly Tibia, PS-Post
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH, MBH, OIY
Dated: August 10, 2023
Received: August 10, 2023

Dear Hollace 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,

Lixin Liu -S

Lixin Liu, 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232414

Device Name

Klassic® Tibial Insert, PS-Post, Klassic All Poly Tibia, PS-Post

Indications for Use *(Describe)*

The Klassic® Knee System is intended for prosthetic replacement in treatment of the following:
• Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis and osteoarthritis
• Patient conditions of inflammatory joint disease (IJD): rheumatoid arthritis
• Patients with failed previous surgery where pain, deformity, or dysfunction persists
• Correctable varus-valgus deformity and moderate flexion contracture
• Revision of a previously failed knee arthroplasty
• Patients who require a total knee replacement

The Klassic® Knee System is indicated for cemented use only, except for the Klassic® Femur, with Cobalt 3D®, the Klassic® Tibial Baseplate with Ti-Coat® and the Universal Cones™ with Ti-Coat®, which are also indicated for cementless use.

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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510(k) Summary

Manufacturer: Total Joint Orthopedics, Inc.
1567 E. Stratford Avenue
Salt Lake City, UT 84106
Phone: 801.486.6070

Contact: Mr. Chris Weaber
Director of Research and Development

Prepared By: MCRA, LLC
803 7th Street NW, Floor 3
Washington, DC 20001
Phone: 202.552.5800

Date Prepared: August 10, 2023

Device Trade Name: Klassic® Tibial Insert, PS-Post, Klassic All Poly Tibia, PS-Post

Device Common Name: Tibial Insert and All Poly Tibia

Classification: 21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

21 CFR 888.3565 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained uncemented prosthesis

Class II

Product Code: JWH, MBH, OIY

Indications for Use:
The Klassic® Knee System is intended for prosthetic replacement in treatment of the following:

- Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis and osteoarthritis
- Patient conditions of inflammatory joint disease (IJD): rheumatoid arthritis
- Patients with failed previous surgery where pain, deformity, or dysfunction persists
- Correctable varus-valgus deformity and moderate flexion contracture
- Revision of a previously failed knee arthroplasty
- Patients who require a total knee replacement

The Klassic® Knee System is indicated for cemented use only, except for the Klassic® Femur, with Cobalt 3D®, the Klassic® Tibial Baseplate with Ti-Coat® and the Universal Cones™ with Ti-Coat®, which are also indicated for cementless use.

Device Description:
The Klassic® Knee System is being updated with additional thicknesses of Tibial Inserts, PS-Post and Additional All Poly Tibia PS-Post implants. Both proposed geometries are fabricated from both Standard Poly and Vitamin E UHMWPE (E-Link).

Predicate Devices:
The modified Klassic® System is substantially equivalent to the primary predicate Klassic® Knee System (K112906), and other identified predicates from the Klassic® Knee System (K162422, K183596) with respect to design, materials, function and indications for use.

Comparison of Technological Characteristics:
The modified Klassic® Knee System features the same materials (GUR 1050 UHMWPE – "Standard Poly" and Vitamin E UHMWPE – "E-Link"), same use in primary or revision Total Knee Arthroplasty, and same EO sterilization compared to the predicate Klassic® Knee System (K112906, K162422, K183596).

Differences include the addition of an All-Poly Tibia, PS-Post implant as compared to the cleared All-Poly Tibia, Ultra-PS and All-Poly Tibia, CR-Congruent versions (K162422), and three additional thicknesses (18, 21, 24mm) added to the already cleared Tibial Inserts, PS-Post (K183956), which are identical in thickness to those of the cleared Tibial Inserts, PS-Max (K202740).

Discussion of Non-Clinical Testing/Performance Data:
Testing and engineering analyses were performed to evaluate the subject components. Additionally, the Klassic® Revision 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:

- Femoral/Tibial Constraint Testing (ASTM F1223)
- Contact Area/Contact Stress (ASTM F2083)
- Post Fatigue Testing
- Range of Motion Evaluation
- Wear (ISO 14243-3)
- Tibial Insert Modular Disassembly Strength (ASTM F1814)

Conclusion:
Testing and engineering analyses showed that the subject components met the pre-determined acceptance criteria identified in the Design Control Activities, demonstrating that the subject components perform as safe and effective compared to the predicate components, and is substantially equivalent to the predicate.