Total Joint Orthopedics, Inc.
Mr. Chris Weaber
Product Development, Regulatory Manager
1567 E. Stratford Avenue
Salt Lake City, Utah 84106

Re: K180929
Trade/Device Name: Klassic HD® 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, LPH, OQG, MBL, LWJ
Dated: April 9, 2018
Received: April 9, 2018

May 9, 2018

Dear Mr. Chris Weaber:

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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K180929

Device Name
Klassic HD® Hip 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.

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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
Fax: 801.486.6117

Contact: Mr. Chris Weaber
Product Development, Regulatory Manager

Prepared By: Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street, NW, Suite 1000
Washington, DC 20001
Phone: 202.552.5800
Fax: 202.552.5798

Date Prepared: May 08, 2018

Device Trade Name: Klassic HD® Hip System

Common Name: Acetabular Shell, Acetabular Insert, Ceramic Femoral Head

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
21 CFR 888.3360 - Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.

Class II

Product Codes: LZO, LPH, OQG, MBL, LWJ

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 intra-operatively. The purpose of this Special 510(k) is to add smaller sizes of the Acetabular Cups, Acetabular Inserts, and Ceramic Femoral Heads and to add both smaller and predicate sizes of Hooded and Low Profile Acetabular Inserts with XLPE material.

**Predicate Devices:**
The modified Klassic HD® Hip System is substantially equivalent to the predicate Klassic HD® Hip System Acetabular Cups with Ti-Coat (K100445), Klassic HD® Acetabular Inserts with E-Link® Poly (K141972), Klassic HD® Acetabular Inserts with XLPE (K161073), Klassic HD® Ceramic Femoral Heads (K143407) and the Klassic HD® Hooded and Low Profile Acetabular Inserts with E-Link® Poly (K173104) with respect to indications, design, materials and function.

**Substantial Equivalence:**
Engineering analysis and testing included burst strength testing, fatigue testing, post-fatigue burst strength testing and pull off testing of ceramic femoral heads per ISO 7206-10. Analysis and testing also included Push out, lever out, axial torque disassembly per ASTM F1820, Range of Motion per ISO 21535, impingement testing per ASTM F2852 and wear testing per ISO 14242, and all results met the pre-determined acceptance criteria identified in the Design Control Activities. The information summarized in the Design Control Activities Summary demonstrates that the modified Klassic HD® Hip System met the pre-determined acceptance criteria for the verification activities. Additionally, the Klassic HD® Hip System is in compliance with LAL testing requirements for orthopedic implants per AAMI ST-72 testing.