DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 19, 2016

Total Joint Orthopedics, Inc.
Mr. Chris Weaber
Manufacturing Development Engineer
1567 East Stratford Avenue
Salt Lake City, Utah 84106

Re: K161073
Trade/Device Name: Klassic HD® Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/ polymer/metal semi-constrained porous-coated uncemented prothesis
Regulatory Class: Class II
Product Code: LPH, MBL, LWJ, LZO
Dated: September 16, 2016
Received: September 19, 2016

Dear Mr. 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 Parts 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
~~Unknown~~ K161073

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

Device Trade Name: Klassic HD® Hip System

Manufacturer:
Total Joint Orthopedics, Inc.
1567 E. Stratford Avenue
Salt Lake City, UT 84106
U.S.A.
Phone: 801.486.6070
FAX: 801.486.6117

Prepared by:
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
Phone: 202.552.5800
Fax: 202.552.5798

Date Prepared: April 15, 2016

Common Name: Hip prosthesis, UHMWPE acetabular insert

Classification: 21 CFR 888.3358, Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
21 CFR 888.3360 Hip Joint femoral (Hemi-hip) metallic cemented or uncemented

Class: Class II

Product Codes: LPH, MBL, LWJ, LZO

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 Total Joint Orthopedics Klassic HD® Acetabular Insert with XLPE ("Insert with XLPE") is a permanently implanted device for use as an acetabular bearing surface in total hip arthroplasty ("THA"). The Insert with XLPE is fully compatible for use with the previously cleared Klassic HD® Hip System and is manufactured from UHMWPE crosslinked by gamma irradiation. The Insert with XLPE is sterilized by ethylene oxide gas and intended for single-use only.

Predicate Devices:

- Total Joint Orthopedics Klassic HD® Hip System (K100445, K141972)

Reference Devices:

- Ortho Development Corporation Escalade Acetabular Cup System (K103384)
- Wright Medical Technology, Inc. LINEAGE® A-CLASS™ (K052026)

Non-Clinical Testing
Non-clinical bench testing was conducted on the Klassic HD® Acetabular Insert with XLPE to support a determination of substantial equivalence to the predicate devices. Testing included extensive material characterization both before and after accelerated aging, sterility validation, and Push Out, Lever Out, Axial Torque Disassembly and Impingement testing with the Klassic HD® acetabular cup, femoral stem and femoral head. Bench testing results demonstrated that the Klassic HD® Acetabular Insert with XLPE is substantially equivalent and does not raise new questions of safety or effectiveness for total hip joint replacement when compared to the predicate devices.

Substantial Equivalence
The Klassic HD® Acetabular Insert with XLPE is substantially equivalent to the predicate devices based on indications for use, technological characteristics, design, material, mechanical performance testing, packaging and sterilization. The information summarized in the performance testing demonstrates that the Klassic HD® Acetabular Insert with XLPE met the pre-determined acceptance criteria. Additionally, LAL testing has been performed to establish that the Klassic HD® Acetabular Inserts with XLPE meet the specified 20EU/device limit.

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