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

October 27, 2017

Re: K173104
Trade/Device Name: Klassic HD® Hooded Acetabular Insert with E-Link® Poly,
Klassic HD® Low Profile Acetabular Insert with E-Link® Poly
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: OQG, LPH, MBL, LWJ
Dated: September 28, 2017
Received: September 29, 2017

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.

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 (DICE) 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173104

Device Name
Klassic HD® Hooded Acetabular Insert with E-Link® Poly
Klassic HD® Low Profile Acetabular Insert with E-Link® Poly

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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1. 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
Product Development, Regulatory Manager

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

Date Prepared: September 29, 2017

Device Trade Name: Klassic HD® Hooded Acetabular Insert with E-Link® Poly
Klassic HD® Low Profile Acetabular Insert with E-Link® Poly

Common Name: Acetabular Insert

Classifications: 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

Class II

Product Codes: OQG, LPH, 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 Total Joint Orthopedics Klassic HD® Hooded Acetabular Insert with E-Link® Poly and Klassic HD® Low Profile Acetabular Insert with E-Link® Poly are permanently implanted devices for use as an acetabular bearing surface in total hip arthroplasty ("THA"). The subject inserts are fully compatible for use with the previously cleared Klassic HD® Hip System and are manufactured from UHMWPE crosslinked by gamma irradiation and infused with vitamin E. The subject inserts are sterilized by ethylene oxide gas and intended for single-use only.

Predicate Devices:
The modified Klassic HD® Hooded Acetabular Inserts with E-Link® Poly and Klassic HD® Low Profile Acetabular Inserts with E-Link® Poly are substantially equivalent to the predicate Klassic HD® Acetabular Inserts with E-Link® Poly (K141972) with respect to indications, design, materials and function. The information summarized in the Design Control Activities Summary demonstrates that the Klassic HD® Hooded Acetabular Inserts with E-Link® Poly and Klassic HD® Low Profile Acetabular Insert with E-Link® Poly meet the pre-determined acceptance criteria for the verification activities.

Substantial Equivalence:
The Klassic HD® Hooded Acetabular Insert with E-Link® Poly and Klassic HD® Low Profile Acetabular Insert with E-Link® Poly are substantially equivalent to the predicate components based on indications for use, technological characteristics, design, material, mechanical performance testing, packaging and sterilization. Verification Activities, including testing and engineering analyses, were performed for Lever out strength, Push Out Strength, Torque Disassembly Strength, Impingement and Wear. The subject Klassic HD® Hooded Acetabular Insert with E-Link® Poly and Klassic HD® Low Profile Acetabular Insert with E-Link® Poly did not create a new worst case as compared to the predicate. The information summarized in the Design Control Activities Summary demonstrates that the Klassic HD® Hooded Acetabular Insert with E-Link® Poly and Klassic HD® Low Profile Acetabular Insert with E-Link® Poly meet 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.