Dear 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

Device Name
Klassic® Knee System

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, Porous, and the Klassic Tibial Baseplate, Porous, which are indicated for cementless use.

Type of Use (Select one or both, as applicable)

- [X] 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.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
5. 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

Date Prepared: January 19, 2018

Device Trade Name: Klassic® Knee System

Device Common Name: Tibial Inserts and Patellae

Classification: 21 CFR 888.3560 – Knee joint patellofemorotibial
polymer/metal/polymer semi-constrained cemented
21 CFR 888.3565 Knee joint patellofemorotibial
metal/polymer porous-coated uncemented prosthesis
Class II

Product Codes: JWH, MBH

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, Porous, and the Klassic Tibial Baseplate, Porous, which are indicated for cementless use.

**Device Description:**
The purpose of this 510(k) is to add Klassic® Knee CR/Congruent Tibial Inserts with E-Link®, Ultra-PS® Tibial Inserts with E-Link®, Sombrero Patellae with E-Link® and Domed Patellae with E-Link® (“E-Link® Knee Components”) to the Klassic® Knee System. These components are manufactured from E-link®, a Vitamin E blended UHMWPE crosslinked by gamma irradiation. The E-Link® Knee Components are available in various sizes and thicknesses to match patient anatomy.

**Predicate Devices:**
The E-Link® Knee Components are substantially equivalent to the predicate Klassic® Knee System Components (K112906, K140942, K150105, K153075, K153310, and K162422) with respect to indications, design, and function. The E-Link material is the same as the E-link material used in the Klassic HD® Acetabular Insert with E-Link Poly (K141972) and Pipeline’s Vitamin E Poly (K112802).

**Substantial Equivalence:**
Engineering analyses and bench testing were performed on E-Link® Knee Components to evaluate wear for the worst case E-Link® Knee Construct, tibial-femoral stability characteristics, stress distributions and range of motion and tibial modular disassembly characteristics, as well as patella-femoral resistance to lateral subluxation and surface stress distribution. The results of these analyses and testing indicate that the E-Link® Knee Components are substantially equivalent to the predicate components. Additionally, the E-Link® Knee Components are in compliance with LAL testing requirements for orthopedic implants.