DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 27, 2016

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

Re: K162256
Trade/Device Name: Klassic® Femur, Porous; Klassic® Tibial Baseplate, Porous
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH
Dated: August 26, 2016
Received: August 29, 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)*
K162256

Device Name
Klassic® Femur, Porous, Klassic® Tibial Baseplate, Porous

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)*

☒ 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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K162256 Klassic Femur, Porous and Klassic Tibial Baseplate, Porous

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
1331 H Street, NW, 12th Floor
Washington, DC 20005
Phone: 202.552.5800
Fax: 202.552.5798

Date Prepared: August 10, 2016

Device Trade Name: Klassic® Femur, Porous
Klassic® Tibial Baseplate, Porous

Device Common Name: Total knee replacement system

Classification: 21 CFR §888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis

Class II

Product Code: 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.

K162256 Klassic Femur, Porous and Klassic Tibial Baseplate, Porous

Device Description:

The Klassic® Femur, Porous and the Klassic® Tibial Baseplate, Porous, are being introduced as line extensions for use with the Klassic® Knee System for uncemented implantation during total knee arthroplasty. The Klassic® Femur, Porous is manufactured from Cobalt-Chromium-Molybdenum alloy and features a cobalt chrome porous sintered coating for uncemented biologic fixation. The Klassic® Tibial Baseplate, Porous is manufactured from Titanium alloy and features a titanium porous sintered coating for uncemented biologic fixation.

Predicate Devices:

The Klassic® Femur, Porous is substantially equivalent to the predicate Klassic® Knee System Femur (K112906) with respect to material, design, and function. The Klassic® Femur, Porous is substantially equivalent to the Exactech® Optetrak One Logic Porous Femoral Component (K153776) and the Wright Medical Advance® Total Knee System porous coated Femoral Components (K061223) with regards to material, function and indications for use without bone cement.

The Klassic® Tibial Baseplate, Porous is substantially equivalent to the predicate Klassic® Knee System Tibial Baseplate (K112906) with respect to material, design, and function. The Klassic® Tibial Baseplate, Porous is substantially equivalent to the Howmedica Osteonics Corp. Triathlon® Tritanium Tibial Baseplates (K123486) and the Wright Medical Advance® Total Knee System porous coated Tibial Component (K061223) with regards to material, function and indications for use without bone cement.

Substantial Equivalence:

Engineering analyses were performed on the Klassic® Femur, Porous and the Klassic® Tibial Baseplate, Porous to evaluate the Tibial-Femoral Stability Characteristics, Stress Distributions and Range of Motion, and Patella-Femoral Resistance to Lateral Subluxation and Surface Stress Distribution, and Tibial Modular Disassembly Characteristics. Non-Clinical testing was performed per ASTM F1800 and per the FDA Guidance Document “Guidance document for testing orthopedic implants with modified metallic surfaces apposing bone or bone cement” dated April 28, 1994. The results of analysis and testing demonstrate that the subject Klassic® Femur, Porous and the Klassic® Tibial Baseplate, Porous, are substantially equivalent to the predicate devices. Additionally, the Klassic® Femur, Porous and the Klassic® Tibial Baseplate, Porous are in compliance with LAL testing requirements for orthopedic implants.