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

March 15, 2019

Re: K190280
Trade/Device Name: Klassic Knee System - Sombrero Patella with Standard Poly, Klassic Knee System - Sombrero Patella with E-Link Poly
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH, MBH, OIY
Dated: February 8, 2019
Received: February 8, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Daniel S. Ramsey -S
2019.03.15 11:38:59 -04'00'

FOR 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)*
K190280

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 with Cobalt 3D™, and the Klassic Tibial Baseplate with Ti-Coat®, 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.

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.

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"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."

TJO Klassic® Knee System – Special 510(k)

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, Suite 1000
Washington, DC 20001
Phone: 202.552.5800

Date Prepared: February 8, 2019

Device Trade Name: Klassic® Knee System

Device Common Name: Polyethylene Patella Component

Classification: 21 CFR 888.3560, Knee Joint Patellofemorotibial Polymer/ metal/ polymer semi-constrained cemented prosthesis
21 CFR 888.3565, Knee joint patellofemorotibial polymer/ metal/ polymer semi-constrained porous coated uncemented prosthesis

Class: II

Product Codes: JWH, MBH, OIY

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 with Cobalt 3D™, and the Klassic Tibial Baseplate with Ti-Coat®, which are indicated for cementless use.

Device Description:
The purpose of this 510(k) is to add size 5, 10mm Sombrero Patella components in Standard Poly and E-Link Poly to be used in conjunction with the Klassic® Knee System during total knee replacement. The components are manufactured from ultrahigh molecular weight polyethylene or Vitamin E blended ultrahigh molecular weight polyethylene with a 40mm diameter and 10mm thickness.

TJO Klassic® Knee System – Special 510(k)

Predicate Devices:

The subject size 5, 10mm Sombrero Patella implants are substantially equivalent to the predicate size 1-4 Sombrero Patellae (K150105 & K180159) with respect to their intended use, material, geometry, and method of fixation. The information summarized in the Design Control Activities Summary demonstrates that the subject size 5, 10mm Sombrero Patellae met the pre-determined acceptance criteria for the verification activities.

Substantial Equivalence:

Engineering analyses were performed on the subject size 5, 10mm Sombrero Patellae to evaluate their conformance, contact area and contact stress, mechanical strength, and peg geometry. The results of these analyses indicate that the subject Sombrero Patellae are substantially equivalent to the predicate Sombrero Patellae. Additionally, the subject components are in compliance with LAL testing requirements for orthopedic implants.