July 23, 2026

Total Joint Orthopedics, Inc.
% Chris Weaber
Founder, Principal Consultant
Arthroplasty Regulatory Consulting
1433 E. Mulberry Way
Sandy, Utah 84093

Re: K261734
Trade/Device Name: Klassic Knee System
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, MBB
Dated: May 26, 2026
Received: May 26, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2026.07.23 11:23:21 -04'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K261734

Device Name
The 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®, the Klassic Tibial Baseplate with Ti-Coat® and the Universal® Cone with Ti-Coat, which are indicated for cementless use.

The Klassic® Knee System is also indicated for temporary use (maximum 180 days) as an adjunct to total knee replacement (TKR) in patients undergoing a two-stage procedure due to a septic process and where gentamicin is the most appropriate antibiotic based on the susceptibility pattern of the infecting micro-organism(s). The Infection Spacer Stem Dowel, Infection Spacer Femur Adapter and Infection Spacer Femur Adapter, Ti are only indicated for this temporary use. These devices are intended for implantation with FDA cleared gentamicin loaded bone cement following implant removal and radical debridement, and in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach for an infection). For the first stage revision, these devices are not intended for use for more than 180 days, at which time they must be explanted and permanent devices implanted, or another appropriate treatment performed (e.g. resection arthroplasty, fusion, etc.). These devices are only indicated for patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers, canes) throughout the implantation period.

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.

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
Consultant

Prepared By: Chris Weaber
Arthroplasty Regulatory Consulting
1433 E. Mulberry Way
Sandy, UT 84093
Phone: 650.922.7326

Date Prepared: July 21, 2026

Device Trade Name: Klassic® Knee System

Device Common Name: Spacer, Dome Extension, Augments, Stem Dowel, Femur Adapter

Classification: 21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

21 CFR 888.3027 Polymethylmethacrylate (PMMA) bone cement.

Class II

Product Code: JWH, MBB

Primary Predicate: Signature Rx Knee System, K240683, 21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Additional Predicate: The Klassic® Knee System, K243991, 21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Additional Predicate: Osteoremedies Remedy Knee Spacer, K183017, 21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

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®, the Klassic Tibial Baseplate with Ti-Coat® and the Universal® Cone with Ti-Coat, which are indicated for cementless use.

The Klassic® Knee System is also indicated for temporary use (maximum 180 days) as an adjunct to total knee replacement (TKR) in patients undergoing a two-stage procedure due to a septic process and where gentamicin is the most appropriate antibiotic based on the susceptibility pattern of the infecting micro-organism(s). The Infection Spacer Stem Dowel, Infection Spacer Femur Adapter and Infection Spacer Femur Adapter, Ti are only indicated for this temporary use. These devices are intended for implantation with FDA cleared gentamicin loaded bone cement following implant removal and radical debridement, and in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach for an infection). For the first stage revision, these devices are not intended for use for more than 180 days, at which time they must be explanted and permanent devices implanted, or another appropriate treatment performed (e.g. resection arthroplasty, fusion, etc.). These devices are only indicated for patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers, canes) throughout the implantation period.

Device Description:
The Klassic® Knee System is being updated with modifications to include additional Infection Spacer, Infection Spacer Dome Extension, Infection Spacer Stem Dowel, Infection Spacer Femur Adapter, and Infection Spacer Femur Adapter, Ti implants.
These proposed geometries are fabricated from Standard Poly (GUR-1050 or GUR-1020 UHMWPE) per ASTM F648 or Titanium Alloy (Ti6Al4V) per ASTM F136.

Comparison of Technological Characteristics:
The modified Klassic® Knee System features the same materials (GUR 1050 UHMWPE, GUR 1020 UHMWPE, and Ti6Al4V), same use in Total Knee Arthroplasty, and same EO or Gamma sterilization compared to the primary predicate Rx Knee System (K240683) and reference predicate Klassic® Knee System (K243991).

The modified Klassic® Knee System is substantially equivalent to the primary predicate Signature Rx Knee System which includes the same indications of Temporary Use (180-day max) as an adjunct to total knee replacement (TKR) in patients undergoing a two-stage procedure due to a septic process.

The subject modified Klassic® Knee System includes components of a total knee system for temporary use similar to the primary predicate. The subject system includes similar but different design features, such as articulations, sizes, and geometries. The subject Stem Dowel is comprised entirely of UHMWPE which differs from the predicate Universal Stem component which is PMMA bone cement with gentamicin with metal reinforcement. The subject Femur Adapters affix to the femoral component with cement which differs from the threaded femoral fixation for the RX Knee System.

The modified Klassic® Knee System is substantially equivalent to the additional predicate device Klassic® Knee System (K243991) with respect to design, materials, function, packaging, and sterilization. The subject Infection Spacer features a threaded interface with the Infection Spacer Dome Extension which differs from the predicate Klassic® All Poly Tibia, Ultra-PS (K243991) which is a monoblock geometry. Additionally, the subject Augment introduces a modified design and material for the predicate Tibial Augment (K243991).

The subject components are substantially equivalent to the additional predicate Osteoremedies Remedy Knee Spacer (K183017) for total Gentamicin implant construct content and feature the same indications for Temporary Use (180-day max). The subject components include UHMWPE and Titanium materials, which differs compared to the predicate Osteoremedies Remedy Knee Spacer (K183017) which is composed entirely of Gentamicin Bone Cement with stainless steel reinforcement.

Discussion of Non-Clinical Testing/Performance Data:
Engineering analyses were performed to evaluate the subject component equivalence to the primary and reference predicates. Additionally, the Klassic® Infection Spacer System implants are in compliance with LAL testing requirements for orthopedic implants.

Engineering analysis conducted to demonstrate substantial equivalence was as follows:

- Femoral/Tibial Constraint Analysis (ASTM F1223)
- Contact Area/Contact Stress Analysis (ISO 21536)
- Range of Motion Evaluation
- Wear Analysis (ISO 14243-3)
- Cement Fixation Analysis
- Subject Infection Spacer Component Thickness per FDA Guidance "Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous Coated Uncemented Prostheses; Guidance for Industry and FDA"
- Volumetric Cement Analysis - Total content of Gentamicin side by side predicate comparison
- Temporary Use: Subject Infection Stem Dowel, Femur Adapter and Femur Adapter, Ti Component Strength and Fixation

Conclusion:
Engineering analyses demonstrated that the subject components met the pre-determined acceptance criteria identified in the Design Control Activities, demonstrating that the subject components perform as safe and effective compared to the predicate components, and are substantially equivalent to the predicates.