December 19, 2025

Ortho Development Corporation
Drew Weaver
Director of Regulatory Affairs
12187 S. Business Park Drive
Draper, Utah 84020

Re: K253161
Trade/Device Name: Balanced Knee System TriMax Porous Femoral Components
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: September 25, 2025
Received: September 26, 2025

Dear Drew Weaver:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Lixin Liu -S

Lixin Liu, Ph.D
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253161

Device Name
Balanced Knee® System TriMax® Porous Femoral Components

Indications for Use *(Describe)*

Balanced Knee® System TriMax® Porous Femoral Components are intended for single use uncemented or cemented total knee arthroplasty with the following indications:

1. Loss of joint configuration and joint function.
2. Osteoarthritis of the knee joint.
3. Rheumatoid arthritis of the knee joint.
4. Post-traumatic arthritis of the knee joint.
5. Valgus, varus, or flexion deformities of the knee joint.
6. Revision procedures where other treatments or devices have failed.

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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510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

Name of the Sponsor:	Ortho Development® Corporation 12187 South Business Park Drive Draper, Utah 84020
510(k) Contact:	Name: Drew Weaver Position: Director of Regulatory Affairs Address: 12187 S. Business Park Drive Draper, UT 84020 USA Telephone: (801) 553-9991 Email: dweaver@orthodevelopment.com
Date Prepared:	November 26, 2025
Submission Type:	Traditional
Proprietary Name:	Balanced Knee® System TriMax® Porous Femoral Components
Common Name:	Knee Femoral Prosthesis (Co-Cr-Mo sintered porous coated knee femoral prosthesis)
Product Code / Classification:	MBH 21 CFR 888.3565: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.
Associated Product Code(s) / Classification:	JWH 21 CFR 888.3560: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
Device Class:	Class II
Primary Predicate Device:	Balanced Knee® System TriMax® CR Femoral Component and E-Vitalize® CR and UC Tibial Inserts (K152169)
Reference Device:	Balanced Knee® System High Flex PS (K123457) Maxx Orthopedics, Freedom® Cementless Femoral Component (K150680)

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1.0 Device Description:

Balanced Knee® System TriMax® Porous Femoral Components are intended for use as part of total knee arthroplasty (TKA) procedures. Total knee arthroplasty is a procedure where worn, diseased, or damaged surfaces of the knee joint are removed and replaced with artificial surfaces.

The components are prescription products consisting of single use devices for implanting into patients in an operating room by a qualified surgeon.

Balanced Knee® System TriMax® Porous Femoral Components are a cobalt-chromium-molybdenum (Co-Cr-Mo) alloy femoral component with Co-Cr-Mo sintered porous coating.

The device will have two configurations:

- Cruciate Retaining (CR) Femoral – (Substantially Equivalent to K152169)
- Posterior Stabilized (PS) Femoral – (Substantially Equivalent to K123457)

They have the same materials of constructions and the same articular geometry as the legally marketed TriMax cemented femoral components. The new feature is the addition of the CoCr porous coating on the bone contacting surfaces that is substantially equivalent to the reference device: Maxx Orthopedics Freedom Porous Femoral Component (K150680).

Balanced Knee® System TriMax® Porous Femoral Components are manufactured from cast Co-Cr-Mo per ASTM F75.

The subject device has a variety of sizes to accommodate variations in patient anatomies: left and right orientations, medial-lateral width (56 – 79.5mm), anterior-posterior width (50 – 74mm), and CR & PS variations.

Balanced Knee® System TriMax® Porous Femoral Components are compatible with BKS® High Flex PS Tibial Inserts (K123457, K131337), BKS® High Flex Patellar Button (K131337), BKS® TriMax® CR and US Tibial Inserts (K152169), and BKS® TriMax® PS Plus Tibial Inserts (K233093).

2.0 Indication for Use:

Balanced Knee® System TriMax® Porous Femoral Components are intended for single use uncemented or cemented total knee arthroplasty with the following indications:

1. Loss of joint configuration and joint function.
2. Osteoarthritis of the knee joint.
3. Rheumatoid arthritis of the knee joint.
4. Post-traumatic arthritis of the knee joint.
5. Valgus, varus, or flexion deformities of the knee joint.
6. Revision procedures where other treatments or devices have failed.

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3.0 Comparison of Technological Characteristic:

Balanced Knee® System TriMax® Porous Femoral Components come in two variations:

- Cruciate Retaining (CR) Femoral – (Substantially Equivalent to K152169)
- Posterior Stabilized (PS) Femoral – (Substantially Equivalent to K123457)

They are manufactured out of Co-Cr-Mo alloy by the same suppliers as these previously cleared devices with the exception of the new porous coating. They have the same articular geometry as these previously cleared devices.

The Co-Cr-Mo porous coating is the same as the previously cleared reference device: Maxx Orthopedics Freedom Porous Femoral Component (K150680).

4.0 Performance Data:

Sterilization

Balanced Knee® System TriMax® Porous Femoral Components are gamma radiation sterilized and are validated to a sterility assurance level of 10^{-6} in accordance with the ISO 11137.

Shelf Life

The packaging for Balanced Knee® System TriMax® Porous Femoral Components are validated in accordance with ASTM D4169.

Biocompatibility

Balanced Knee® System TriMax® Porous Femoral Component's biocompatibility was established according to the requirements of ISO 10993-1 and found to be safe for its intended use.

Mechanical Testing

The following non-clinical mechanical tests and analyses were conducted on the subject device.

Range of Motion Test (ASTM F2083)	ASTM F2083
Femorotibial Constraint (ASTM F1223)	ASTM F1223
Femorotibial Contact Area (ASTM F2083)	ASTM F2083
Patellofemoral Constraint (ASTM F1672)	ASTM F1672
Patellofemoral Contact Area (ASTM F1672)	ASTM F1672
Femoral Fatigue Strength (ASTM 3210)	ASTM F3210
Wear Testing (ISO 14243)	ISO 14243
Porous Coating Characterization	ASTM F1854

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Porous Coating Static Shear and Tensile	ASTM F1044 & F1147
Porous Coating Abrasion	ASTM F1978
Porous Coating Shear Fatigue	ASTM F1160

Clinical Testing

No clinical testing is required to establish the safety and effectiveness of Balanced Knee® System TriMax® Porous Femoral Components.

5.0 Substantial Equivalence Conclusion:

Verification and validation activities were conducted to establish the performance of Balanced Knee® System TriMax® Porous Femoral Components. The results of verification and validation activities demonstrate that Balanced Knee® System TriMax® Porous Femoral Components are as safe and effective and perform as well as the legally marketed predicates.

Based on similarities in indication for use/intended use, technological characteristic, basic design, device material, and principle of operation, Balanced Knee® System TriMax® Porous Femoral Components are considered substantially equivalent to the previously cleared predicate devices.