October 25, 2023

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

Re: K233093
Trade/Device Name: Balanced Knee® System TriMax PS Plus Tibial Insert
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
Dated: September 25, 2023
Received: September 26, 2023

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.

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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2023.10.25 21:09:55 -04'00'

FOR: 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K233093

Device Name
BKS TriMax® PS Plus Tibial Insert

Indications for Use *(Describe)*

The Balanced Knee System TriMax PS Plus Tibial Insert is indicated for use in cemented total knee arthroplasty procedures with the following indications:

1. Loss of knee 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.

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Section 5

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 Telephone: (801) 553-9991 Email: DWeaver@orthodevelopment.com
Date Prepared:	September 25, 2023
Submission Type:	Special 510(k)
Proprietary Name:	Balanced Knee® System TriMax PS Plus Tibial Insert
Common Name:	Total Knee Replacement Prosthesis
Classification:	21 CFR 888.3560, Knee joint, patellofemorotibial, polymer/metal/polymer semi-constrained cemented prosthesis
Device Class:	Class II
Device Product Code:	JWH
Predicate Devices:	K131337 - Balanced Knee® System High Flex Vitamin E PS Tibial Insert

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ORTHO DEVELOPMENT®

5.1 Device Description:

The Balanced Knee® System (BKS) TriMax PS Plus Tibial Insert is a line extension of the TriMax PS Tibial Insert (K131337) that offers slightly more constraint than the original PS Insert.

The PS post geometry is the only design difference between the previously cleared predicate device and the subject device. The change slightly modifies the post's shape to provide additional internal/external and varus/valgus constraint if the surgeon determines the need exists. The balance of the design is identical including the articulating surface, locking mechanism, as well as the PS post location and height.

The PS Plus inserts are intended for use in primary and revision knee surgeries with the same indications for use as the predicate.

This implant is used with existing BKS and BKS Revision (BKSR) tibial trays, TriMax femoral components and the BKSR modular femoral components.

The material is identical as well as all manufacturing processes, cleaning, sterilization and packaging that were cleared under K131337.

5.2 Indication for Use:

The Balanced Knee® System TriMax PS Plus Tibial Insert is indicated for use in cemented total knee arthroplasty procedures with the following indications:

1. Loss of knee 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.

5.3 Comparison of Technological Characteristics:

The PS Plus is technologically similar to the predicate PS Tibial Insert (K131337) in terms of indication for use/intended use, technological characteristics, design, material, and principle of operation.

The post design was evaluated using well established methods and recognized consensus standards to confirm that it meets the original design requirements of the predicate.

Specifically, the following areas were evaluated:

- Geometric Analysis
- Contact Area and Pressure

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- Constraint
- Wear
- Range of Motion
- PS Post Fatigue

The material is identical to the predicate as well as all manufacturing processes, cleaning, sterilization, and packaging.

The results showed similar or identical performance indicating that the design outputs of the PS Plus Tibial Insert meet the design inputs.

5.4 Performance Data:

Sterilization

PS Plus Tibial Inserts are sterilized using ethylene oxide with a Sterilization Assurance Level (SAL) of 10^{-6} in accordance with ISO 11135-1.

Shelf Life

The packaging of the PS Plus Tibial Insert is validated in accordance with ASTM D4169:2016 – Standard Practice for Performance Testing of Shipping Containers and Systems.

Biocompatibility

The PS Plus Tibial Inserts is suitable for implantation as verified according to ISO 10993.

5.5 Substantial Equivalence Conclusion:

Verification and validation has been conducted according to design control procedures within a risk analysis framework to determine that the design outputs meet the design inputs using the same test criteria and methodology as the predicate K131337.

Based on similarities in indication for use/intended use, technological characteristic, basic design, device material, and principle of operation, the PS Plus Tibial Insert is considered substantially equivalent to the previously cleared predicate devices.