December 16, 2021

Ortho Development Corporation
Drew Weaver
Director of Regulatory & Clinical Affairs
12187 South Business Park Drive
Draper, Utah 84020

Re: K211471
Trade/Device Name: Balanced Knee® System Uni
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee Joint Femorotibial Metal/Polymer Non-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSX
Dated: November 10, 2021
Received: November 12, 2021

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 (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/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 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 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,

Ting Song, Ph.D., R.A.C.
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)*

K211471

Device Name
Balanced Knee® System Uni

Indications for Use *(Describe)*

1. Non-inflammatory degenerative joint diseases (NIDJD), e.g., osteoarthritis, avascular necrosis
2. Traumatic arthritis
3. Previous tibial condyle or plateau fracture with loss of anatomy or function
4. Varus deformities
5. Revision of the tibial bearing insert of a previously implanted unicompartmental knee system provided that the tibial tray mechanism is not compromised, and femoral and tibial tray components remain well fixed and undamaged.

The BKS Uni is intended for unicompartmental knee arthroplasty procedures. The system is single-use and intended for implantation with bone cement.

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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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) Primary Contact:	Name: Divya Palan Position: Regulatory Affairs Specialist Telephone: (617) 459-9652 Email: DPalan@orthodevelopment.com
510(k) Secondary Contact:	Name: Darlene Hull Position: Director of Regulatory and Clinical Affairs. Telephone: (801) 619-3499 Email: DHull@orthodevelopment.com
Date Prepared:	May 10, 2021
Submission Type:	Traditional 510(k)
Proprietary Name:	Balanced Knee® System Uni
Common Name:	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Classification:	21 CFR 888.3520
Device Class:	Class II
Device Product Code:	HSX
Primary Predicate Device:	Zimmer Unicompartmental Knee System (K033363)
Secondary Predicate Device:	EMPOWR Partial Knee System (K191325)

5.1 Device Description:

The Balanced Knee® System (BKS®) Uni is a single compartment knee replacement. The BKS Uni is indicated for cemented use only.

Cobalt Chromium Femoral Component
The femoral components are cobalt chromium (Co-Cr-Mo). The femoral components are right and left specific and are intended for cemented use only.

Titanium Tibial Trays
The titanium tibial trays (Ti-6Al-4V ELI) are left and right specific and are for cemented use only.

Polyethylene Tibial Insert
The E-Vitalize tibial insert is manufactured from crosslinked Vitamin E Ultra High Molecular Weight Polyethylene. The inserts match the respective size of the tibial tray used.

5.2 Indication for Use:

1. Non-inflammatory degenerative joint diseases (NIDJD), e.g., osteoarthritis, avascular necrosis
2. Traumatic arthritis
3. Previous tibial condyle or plateau fracture with loss of anatomy or function
4. Varus deformities
5. Revision of the tibial bearing insert of a previously implanted unicompartmental knee system provided that the tibial tray mechanism is not compromised, and femoral and tibial tray components remain well fixed and undamaged.

The BKS Uni is intended for unicompartmental knee arthroplasty procedures. The system is single-use and intended for implantation with bone cement.

5.3 Comparison of Technological Characteristic:

The Balanced Knee® System Uni is technologically similar to the already cleared predicate device Zimmer Unicompartmental Knee System (K033363) and EMPOWR Partial Knee System (K191325) in terms of indication for use/intended use, technological characteristics, basic design, device material, and principle of operation.

5.4 Performance Data:

Sterilization

The Balanced Knee® System Uni is gamma radiation and ethylene oxide sterilized and was validated to a sterility assurance level of 10^{-6} in accordance with the following standards:

- ISO 11137-1:2006, Am1:2013, Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization; and
- ISO 11137-2:2013, Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose.
- ISO 11135:2014/Amd.1:2018(E), Sterilization of health-care products – Requirements for the development, validation and routine control of sterilization process for medical devices.

Validation results indicate that the Balanced Knee® System Uni complies with the standards.

Shelf Life

The packaging of Balanced Knee® System Uni was validated in accordance with the following standards:

- ISO 11607-1:2006 Packaging for terminally sterilized medical devices – Part 1: requirements for materials, sterile barrier systems and packaging systems; and
- ISO 11607-2:2006 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes.

Validation results indicate that the packaging for the Balanced Knee® System Uni complies with the standards.

Biocompatibility

The Balanced Knee® System Uni contact materials were verified in accordance with the following standards:

- ISO 10993-1:2009, Biological evaluation of medical device – Part 1: Evaluation and testing within a risk management process.

Validation results indicate that the biological evaluation complies with the standard.

Mechanical Testing

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

- Range of Motion Test
- Constraint Test
- Component Interlock Strength Test
- Tibial Component Fatigue Test
- Contact Area/Stress Test
- Femoral Fatigue Test
- Wear Test Analysis

Clinical Testing

No clinical testing of the Balanced Knee® System Uni has been conducted.

5.5 Substantial Equivalence Conclusion:

Verification and Validation activities were conducted to establish the performance of Balanced Knee® System Uni. The results of these activities demonstrate that Balanced Knee® System Uni is as safe, as effective, and performs 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 Uni is considered substantially equivalent to the previously cleared predicate devices.