Ortho Development Corporation
Adrienne Von Foller
Sr. Regulatory Affairs Specialist
12187 So. Business Park Drive
Draper, Utah 84020

October 31, 2018

Re: K182085
Trade/Device Name: Balanced Knee Revision System Trabecular Tibial Cone Augments
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
Dated: August 1, 2018
Received: August 2, 2018

Dear Adrienne Von Foller:

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
2018.10.31 14:59:18
-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)*

K182085

Device Name

Balanced Knee® Revision System Trabecular Tibial Cone Augments

Indications for Use *(Describe)*

These devices are intended for use in total knee arthroplasty procedures for the following conditions:

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.

The BKS Revision is indicated in the salvage of previously failed surgical attempts where bone loss may require the use of augments, sleeves, cones or stem extensions.

The BKS Revision System Trabecular Tibial Cone Augments are for cemented or 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

12187 So. Business Park Drive
Draper, Utah 84020
801-553-9991/ fax 553-9993
Orthodevelopment.com

510(k) Summary

Name of Sponsor:	Ortho Development Corporation 12187 South Business Park Drive Draper, Utah 84020
510(k) Contact:	Adrienne von Foller Senior Regulatory Affairs Specialist Telephone: (801) 619-8933 Email: RA@OrthoDevelopment.com
Date Prepared:	July 30, 2018
Submission Type:	Traditional 510(k)
Proprietary Name:	Balanced Knee® Revision System Trabecular Tibial Cone Augments
Common Name:	Knee Joint Replacement Prosthesis
Classification:	21 CFR 888.3560: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis 21 CFR 888.3565: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Device Class:	Class II
Device Product Code:	JWH, MBH
Predicate Device:	K053340, K102896 – Trabecular Metal Tibial Cone Augments; Zimmer®, Inc.
Reference Device:	K132312 – Tesera Trabecular Technology (T^3) Acetabular Shell System; Renovis® Surgical Technologies, Inc.

5.1 Device Description

The Balanced Knee® Revision System (BKS® Revision) Trabecular Tibial Cone Augments are an addition to the Balanced Knee® Revision System to provide optional single-use modular cone augment implants used in revision knee surgery. The subject device provides additional support to the tibial implant and reinforcement to the proximal tibia when bone voids are present. The subject device is designed for cemented or uncemented fixation with the bone.

5.2 Indications for Use

The subject device is intended for use in total knee arthroplasty procedures for the following conditions:

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.

The BKS Revision is indicated in the salvage of previously failed surgical attempts where bone loss may require the use of augments, sleeves, cones or stem extensions.
The BKS Revision System Trabecular Tibial Cone Augments are for cemented or cementless use.

5.3 Basis for Substantial Equivalence:

The BKS® Revision Trabecular Tibial Cone Augments have the same technological characteristics as the predicate device. These include:

1. Indications for use
2. Intended use
3. Basic principles of operation
4. Basic design
5. Sterilization

The following non-clinical tests were conducted and successfully met the predetermined acceptance criteria:

1. Tibial construct fatigue per ASTM F2083 and ASTM F1800
2. Static compression
3. Mechanical testing per ASTM F1044, ASTM F1147, and ASTM F1160
4. Porous structure analysis per ASTM F1854
5. Tensile properties and composition of material per ASTM F136 and ASTM F3001
6. Abrasion resistance per ASTM F1978
7. Bacterial endotoxin testing using LAL pyrogen testing methodology per ANSI/AAMI ST72

Note: Where testing was performed according to a recognized consensus standard, the designation number of the standard is referenced above.

The fundamental scientific technology of the BKS® Revision Trabecular Tibial Cone Augments is the same as the previously cleared predicate. The test results further demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate. No clinical studies were deemed necessary for a determination of substantial equivalence.

The intended use of the subject device is the same as the predicate. Based on similarities in indications for use, basic design, and the principle of operation, the BKS® Revision Trabecular Tibial Cone Augments are substantially equivalent to the previously cleared predicate device.