Ortho Development Corporation
Dan Petersen
Regulatory Affairs Specialist
12187 So. Business Park Drive
Draper, Utah 84020

June 20, 2018

Re: K180743
Trade/Device Name: Balanced Knee Revision System - Offset Junction Box
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: March 20, 2018
Received: March 22, 2018

Dear Dan Petersen:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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,

Mark N. Melkerson -S

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)*

K180743

Device Name
Balanced Knee® Revision System - Offset Junction Box

Indications for Use *(Describe)*

This 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.

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.

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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:	Dan Petersen Regulatory Affairs Specialist Telephone: (801) 619-3416 Facsimile: (801) 619-8916 Email: RA@OrthoDevelopment.com
Date Prepared:	March 20, 2018
Submission Type:	Traditional 510(k)
Proprietary Name:	Balanced Knee® Revision System - Offset Junction Box
Common Name:	Offset Junction Box
Classification:	21 CFR 888.3560: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
Device Class:	Class II device
Device Product Code:	JWH
Predicate Devices:	K060569 – Balanced Knee Revision System, Stem Junction Box; Ortho Development Corporation

5.1 Device Description

The Offset Junction Box is part of the Balanced Knee® Revision System and is a single use modular device used in revision knee surgery to provide an attachment point between a modular femoral component and a stem extension.

The Offset Junction Box is available in four size options: 0mm and 5mm offset configurations with either a 5° or 7° valgus angle.

5.2 Indications for Use

This 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.

5.3 Basis for Substantial Equivalence:

The Offset Junction Box has the same technological characteristics as the predicate device. These include:

1. Indications for use
2. Intended use
3. Basic design
4. Function
5. Manufacturer
6. Manufacturing Process
7. Sterilization
8. Packaging

The following non-clinical mechanical tests were conducted on the worst-case configurations of the Offset Junction Box:

1. Static torsion per ASTM F-1814
2. Static axial and shear per ASTM F-1814
3. Cyclic fatigue per ASTM F-1814

Bacterial endotoxin testing was also performed using LAL pyrogen testing methodology and met the predetermined acceptance criteria.

The fundamental scientific technology of the Offset Junction Box is the same as the previously cleared device. The mechanical test results demonstrate that the Offset Junction Box is safe and effective.

Based on similarities in intended use, design, manufacturing methods, sterilization, packaging, and the mechanical test results, the Offset Junction Box is substantially equivalent to the predicate device that was cleared under K060569.