October 25, 2024

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

Re: K242984
Trade/Device Name: BKS Revision System
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: October 25, 2024
Received: September 26, 2024

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 and Part 809); 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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2024.10.25 15:56:31 -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)*
K242984

Device Name
BKS Revision System

Indications for Use *(Describe)*

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, BKS TriMax, and BKS Revision are intended for total knee arthroplasty procedures.

The BKS is indicated in the salvage of previously failed surgical attempts where bone loss does not require the use of augments or stem extensions and where collateral ligaments may be relied upon for medial/lateral (M/L) stability.

BKS TriMax is intended in the salvage of previously failed surgical attempts where bone loss does not require the use of augments or stem extensions, where collateral ligaments may be relied upon for medial/lateral stability, where postoperative flexion up to 150° may be desirable, and the patient meets all indications/contraindications requirements.

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

The BKS Revision system is indicated for cemented use only. The porous-coated metaphyseal sleeves are intended for cemented and uncemented applications.

The BKS Revision CK Tibial Insert is indicated for use with the BKS Revision Modular femoral and Modular, Offset, or Sleeve tibial components where collateral ligaments may not be relied upon for medial/lateral (M/L) stability.

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 8402
801-553-9991/ fax 553-999
Orthodevelopment.com

ORTHO DEVELOPMENT®

510(k) Summary of Safety & Effectiveness

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:	October 25, 2024
Submission Type:	Special
Proprietary Name:	BKS Revision System
Common Name:	BKS Revision Sleeve Junction Box
Product Code / Classification:	JWH Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer 21 CFR 888.3560: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
Associated Product Code(s) / Classification:	MBH Prosthesis, knee, patello/femorotibial, semi-constrained, uncemented, porous, coated, polymer/metal/polymer 21 CFR 888.3565: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.
Device Class:	Class 2
Primary Predicate Device:	BKS® Revision Sleeves System (K181569)

12187 So. Business Park Drive
Draper, Utah 8402
801-553-9991/ fax 553-999
Orthodevelopment.com

1.0 Device Description:

The purpose of this special 510(k) submission is to request clearance for BKS Revision Sleeve Junction Box of the BKS Revision System which is an extension of Ortho Development's previously cleared predicate BKS Revision Sleeves System (K181569).

The subject device incorporates the same locking taper interface for mating with the BKS Revision Sleeves and the same principle of operation for locking the A/P position relative to the BKS Revision Modular Femoral Component. The subject device is manufactured in the same manner from the same material. The subject device also employs the same packaging components and sterilization method.

Differences between the subject and predicate device include small adjustments to the envelope geometry, internal configuration, and driving feature for assembly during use. These changes have been made to optimize the Sleeve Junction Box for use specifically with femoral sleeves. The mechanics of the connection and locking mechanism are the same as the predicate device.

2.0 Indication for Use:

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, BKS TriMax, and BKS Revision are intended for total knee arthroplasty procedures.

The BKS is indicated in the salvage of previously failed surgical attempts where bone loss does not require the use of augments or stem extensions and where collateral ligaments may be relied upon for medial/lateral (M/L) stability.

BKS TriMax is intended in the salvage of previously failed surgical attempts where bone loss does not require the use of augments or stem extensions, where collateral ligaments may be relied upon for medial/lateral stability, where postoperative flexion up to 150° may be desirable, and the patient meets all indications/contraindications requirements.

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

The BKS Revision system is indicated for cemented use only. The porous-coated metaphyseal sleeves are intended for cemented and uncemented applications.

12187 So. Business Park Drive
Draper, Utah 8402
801-553-9991/ fax 553-999
Orthodevelopment.com

The BKS Revision CK Tibial Insert is indicated for use with the BKS Revision Modular femoral and Modular, Offset, or Sleeve tibial components where collateral ligaments may not be relied upon for medial/lateral (M/L) stability.

3.0 Comparison of Technological Characteristic:

The Sleeve Junction Box is technologically the same as the already cleared Tapered Junction Box that was a component of BKS Revision Sleeves (K181569). It is the same in terms of indications for use/intended use, basic design, device materials, and principles of operation.

Differences between the subject and predicate device include small adjustments to the envelope geometry, internal configuration, and driving feature for assembly during use. These changes have been made to optimize the Sleeve Junction Box for use specifically with femoral sleeves. The mechanics of the connection and locking mechanism are the same as the predicate device.

Labeling, packaging and sterilization do not change.

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

4.0 Performance Data:

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

The evaluation includes: geometric analysis, axial fatigue strength per ASTM F1814, disassembly strength, assembly evaluation, and packaging evaluation.

These performance data demonstrate that the original design inputs of the predicate are met.

5.0 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 K181569.

Based on similarities in indication for use/intended use, technological characteristic, basic design, device material, and principle of operation, the BKS Revision Sleeve Junction Box of the BKS Revision System is considered substantially equivalent to the previously cleared predicate device.