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

10/12/2018

Re: K181569
Trade/Device Name: BKS Revision Sleeves 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: June 13, 2018
Received: September 13, 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. 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
2018.10.12 11:12:21 -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)*
K181569

Device Name
BKS Revision Sleeves System

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 or stem extensions.

The BKS Revision is indicated for cemented application only. The porous-coated metaphyseal sleeves are intended for cemented and uncemented biological fixation application.

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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Orthodevelopment.com

Section 5
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 Email: RA@OrthoDevelopment.com
Date Prepared:	August 8, 2018
Submission Type:	Traditional 510(k)
Proprietary Name:	BKS® Revision Sleeves System
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
Device Product Code:	JWH, MBH
Primary Predicate Device:	BKS® Revision Knee System; Ortho Development (K031201, K060569, K103837)
Additional Predicate Device:	ATTUNE® Revision Knee System; DePuy (K160700) Vanguard® 360 OsseoTi™ Tibial Sleeve Augments, Biomet (K140883)

5.1 Device Description

The BKS® Revision Sleeves System expands the capabilities of the Balanced Knee® System (BKS®) Revision through the introduction of femoral and tibial sleeves, a tapered junction box, locking bolt, and a sleeve specific tibial tray. All new implants are a single-use modular system used in revision knee surgery to accommodate metaphyseal bone defects and provide rotational stability. The system is designed for cemented or uncemented fixation with the bone. The porous-coated femoral sleeve is affixed to the modular femoral component via a tapered junction box. The porous-coated tibial sleeve is affixed to a sleeve tibial tray.

5.2 Indications for Use

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 or stem extensions.

The BKS Revision is indicated for cemented application only. The porous-coated metaphyseal sleeves are intended for cemented and uncemented biological fixation application.

5.3 Basis for Substantial Equivalence:

The BKS Revision Sleeves System has the same technological characteristics as the predicates. These include:

- Indications for use
- Intended use
- Basic design
- Function
- Manufacturer
- Manufacturing Process
- Packaging
- Sterilization

The following non-clinical tests were conducted on the worst-case configurations of the BKS Revision Sleeves System and successfully met the predetermined acceptance criteria:

- Static Disassembly per ASTM F-1814 and ASTM F-2083
- Cyclic fatigue per ASTM F1800, ASTM F1814, and ASTM F2083
- Bacterial endotoxin testing using LAL pyrogen testing methodology per ANSI/AAMI ST72:2011

The fundamental scientific technology of the BKS Revision Sleeves System is the same as the previously cleared predicates. The test results demonstrate that the BKS Revision Sleeves System is as safe, as effective, and performs as well as or better than the legally marketed predicates. No clinical studies were performed.

Based on similarities in intended use, design, manufacturing methods, sterilization, packaging, and the mechanical test results, the BKS Revision Sleeves System is substantially equivalent to the previously cleared predicates.