September 11, 2024

Signature Orthopaedics Pty Ltd
Declan Brazil
Managing Director
7 Sirius Road
Lane Cove, NSW 2066
Australia

Re: K240683
Trade/Device Name: Rx Knee 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, MBB
Dated: August 14, 2024
Received: August 14, 2024

Dear Dr. Brazil:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2024.09.11 10:55:43 -04'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240683

Device Name

Rx Knee System

Indications for Use *(Describe)*

The patient should be skeletally mature to receive a knee replacement. The Rx Knee System is indicated for temporary use (maximum 180 days) as an adjunct to total knee replacement (TKR) in patients undergoing a two-stage procedure due to a septic process and where gentamicin is the most appropriate antibiotic based on the susceptibility pattern of the infecting micro-organism(s). The device is intended for use in conjunction with systemic antimicrobial therapy (standard treatment approach to an infection).

The device is intended for use with the gentamicin-loaded cement, Palacos® G.

The Rx Knee System is not intended for use for more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g., resection arthroplasty, fusion etc.).

The device is only indicated for patients who will consistently use traditional mobility assist devices (e.g., crutches, walkers, canes) throughout the implantation period, allowing basic joint mobility.

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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510(k) SUMMARY

Manufacturer:	Signature Orthopaedics Pty Ltd 7 Sirius Road Lane Cove, NSW 2066 Australia Signature Orthopaedics Europe Ltd Unit A, IDA Business & Technology Park Garrycastle Athlone Westmeath N37 DY26 IRELAND
Device Trade Name:	Rx Knee System
Common Name:	Temporary Knee Prosthesis
Contact:	Dr. Declan Brazil Managing Director of Signature Orthopaedics
Prepared By:	Signature Orthopaedics Pty Ltd 7 Sirius Road Lane Cove, NSW 2066 Australia Phone: +61 (2) 9428 5181 Fax: +61 (2) 8456 6065
Date Prepared:	September 10, 2024
Classification:	**Primary Product Code** Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (JWH, 21CFR 888.3560) **Secondary Product Code** Polymethylmethacrylate (PMMA) bone cement (MBB, 21CFR 888.3027)
Primary Devices:	Primary Predicate • Remedy Stemmed Knee Spacer (K183017) Predicate/Reference Device • ATTUNE Revision Fixed Bearing (K160700) • World Knee System (K181530, K220737, K223062)

Device Description:
The Rx Knee System is a temporary knee device consisting of femoral, all polyethylene tibial and patellar components, with femoral and tibial augments and a tibial or universal stem to accommodate for variants in patient anatomy. The femoral component is available in posterior stabilised and cruciate retaining variants intended for use with corresponding all polyethylene tibia variants that have been previously cleared as part of Signature Orthopaedics' World Knee System via K181530. The femoral and tibial components have been previously cleared as part of Signature Orthopaedics' World Knee System via K181530, K220737 and K223062. All Rx Knee System components are intended for use with FDA-cleared gentamicin-loaded bone cement.
The device is intended to be used for patients undergoing a two-stage revision procedure for infection of a total knee implant. The Rx Knee System components are sterile, single-use devices intended for temporary use as a total knee replacement.

Materials: Cast Cobalt Chromium (CoCr) alloy (ASTM F75 and ISO 5832-4) for the femoral component, Wrought Titanium-6Aluminium-4Vanadium ELI Alloy (Ti6Al4V ELI, ASTM F136-13) for femoral and tibial augment components, tibial stem, stem extension adapter and locking screw, Ultra-High-Molecular-Weight Polyethylene (UHMWPE) or Vit-E HXLPE for the femoral and tibial components and All-poly tibial components previously cleared as part of predicate World Knee System, and titanium nitride (TiN) diamond-like carbon (DLC) for coating femoral components which is the subject of FDA device master file no. 1647.

Indications for Use:
The patients should be skeletally mature to receive a knee replacement. The Rx Knee is indicated for temporary use (maximum 180 days) as an adjunct to a total knee replacement (TKR) in patients undergoing a two-stage procedure due to a septic process and where gentamicin is the most appropriate antibiotic based on the susceptibility pattern of the infecting micro-organism(s).

The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The device is intended for cemented use with the gentamicin-loaded cement, Palacos® G.

The Rx Knee System is not intended for use for more than 180 days, at which time it should be explanted and a permanent device implanted or another appropriate treatment performed (e.g. resection arthroplasty, fusion etc.).

The device is only indicated for patients who will consistently use traditional mobility assist devices (e.g., crutches, walkers, canes) throughout the implantation period, allowing basic joint mobility.

Intended Use:
The Rx Knee System is intended for temporary use (maximum 180 days) as a total knee replacement in patients undergoing a two-stage procedure due to a septic process. This is the same intended use as the primary predicate OsteoRemedies Remedy Stemmed Knee Spacer.

Comparison of Technological Characteristics:
The subject device femoral components are identical in geometry and main material to predicate World Knee System symmetrical femoral components which have been cleared as part of the World Knee System via K223062 and originally K181530. The all polyethylene tibial components have been previously cleared as part of the World Knee System via K220737 and originally K181530.
The subject device femoral and tibial components have similar overall dimensions and condylar geometry to the femoral and tibial components of Remedy Stemmed Knee Spacer and ATTUNE Revision Knee. The only difference between the subject device and the primary predicate Remedy Stemmed Knee Spacer is the material composition since the predicate device is composed entirely of PMMA and MMA bone cement. The subject femoral and tibial components are intended for cemented fixation using gentamicin-loaded bone cement, which is similar to the constituting material of the predicate femoral and tibial components.

The subject device femoral and tibial augment components of various sizes are similar to the augments that are part of the ATTUNE Revision Knee System. The predicate World Knee System does not consist of augments since it is intended for for primary knee replacement. The predicate Remedy Stemmed Knee Spacer does not consist of augments, however subject device femoral and tibial augments are designed to achieve the same function as the independent components (femoral component, tibial component and stem extension components) of the predicate device that can be combined with each other depending on the anatomy of the patient.

The subject device universal stem component is similar to the stem component of predicates Remedy Stemmed Knee Spacer and ATTUNE Revision Knee System. The stem has the same straight design and material as the ATTUNE Revision Knee System, with similar diameter options. The predicate World Knee System does not consist of a stem component since it is intended for primary knee replacement. The subject device stem component varies from predicate Remedy Stemmed Knee Spacer with regards to the material as the predicate component is PMMA bone cement with gentamicin with stainless steel reinforcement. However, this difference in technological characteristic does not impact the intended use. The subject device universal stem is intended to be used with gentamicin-loaded bone cement. Hence, the

overall structure of both device stem components will have a metallic core with gentamicin-loaded bone cement.

Performance Testing:
Engineering evaluations were conducted to verify that the performance of the Rx Knee System with respect to mechanical performance, biocompatibility, sterility and antibiotic elution, is as safe and effective as the predicate devices and therefore adequate for anticipated in-vivo use. The following V&V activities were conducted:

- Review of performance testing of the referenced predicate World Knee System components previously cleared as part of K223062, K220737 and K181530, to verify that the Rx Knee System device falls within scope of the following performance testing:
    - Range of motion analysis
    - Component contact area and stress testing
    - Tibial post stress testing

  The subject device is intended for temporary use (<180 days), and the expected physiological loading on the subject device is less than the reference predicate World Knee System because the Rx Knee System is intended for use with traditional mobility assistance devices for the entire duration of the implant, reducing the amount of direct loading on the patient's knee joint.
- Comparison of subject device components to the referenced predicate World Knee System components previously cleared as part of K220737, K223062 and K181530 with respect to materials and manufacturing methods (formulation, processing, sterilisation and body/fluid contact) to verify that the device does not raise biocompatibility concerns.
- Evaluation of subject components for sterilisation difficulty to verify that the subject device does not present a new worst case for sterilisation validation.
- Volumetric evaluation, including a side by side comparison of the total dosage of antibiotics released into the body for the subject device and the primary predicate cement spacer (K183017) using the indicated gentamicin bone cement to verify that the device does not represent a worst-case for antibiotic dosage.

The results of this non-clinical testing including engineering evaluations show that the subject Rx Knee System is as safe, as effective and is expected to perform at least as well as the primary predicate cement spacer (K183017).

Substantial Equivalence Conclusion:
Based on comparability of indications for use and pertinent technological characteristics the Rx Knee System is substantially equivalent to its predicate devices cited herein. Any differences do not raise new questions of safety and effectiveness as established with performance testing; the subject device is at least as safe and effective as the legally marketed predicate devices.