April 11, 2022

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

Re: K220737
Trade/Device Name: World Knee Total 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, MBH, OIY
Dated: March 7, 2022
Received: March 14, 2022

Dear Declan 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 (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/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,

Ting Song, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220737

Device Name
World Knee Total Knee System

Indications for Use *(Describe)*
The patient should be skeletally mature to receive a knee replacement. Patients should have adequate bone stock and size to support and accept the prosthesis.

The patient's need for knee replacement should be due to one or more of the following conditions:

- Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis.
- Inflammatory degenerative joint disease including rheumatoid arthritis.
- Functional deformity such as varus, valgus or flexion deformities.
- Revision procedures where other treatments or devices have failed.
- Fractures that are unmanageable using other techniques.

Signature Orthopaedic's World Knee replacement components may be intended for cemented or cementless use. Please verify whether the particular component is intended for cemented or cementless use by checking the package label.

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.

1 510(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:	World Knee Total Knee System
Common Name:	Total 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:	March 7th, 2022
Classification:	Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis (JWH, 21 CFR 888.3560) Knee Joint Patellofemorotibial Semi-Constrained, Uncemented, Porous, Coated, Polymer/Metal/Polymer (MBH, 888.3565) Knee Joint Patellofemorotibial Semi-Constrained, Cemented, Polymer + Additive/Metal/Polymer + Additive (OIY, 888.3560)
Predicate Devices:	Primary Predicate • Signature Orthopaedics World Knee Total Knee System (K190577), Modular Titanium Baseplate • Signature Orthopaedics World Knee Total Knee System (K181530), All Poly Tibial Baseplate Additional Predicate • Signature Orthopaedics World Knee Total Knee System (K180570)

Device Description:

The World Knee Total Knee System is a modular knee system consisting of a femoral component, meniscal insert, a patella and a tibial baseplate or all polyethylene tibia. The femoral component and meniscal inserts are available as posterior Stabilized or cruciate retaining variants. Cruciate retaining meniscal inserts are available as standard or ultracongruent designs. The tibial baseplate components covered in this 510(k) is made of Titanium as part of the cemented version. The patella components are available in a spherical or non-symmetrical designs.

The primary purpose of this Special 510(k) Device Modification to the World Knee System is to notify the FDA of the change in materials used to manufacture the tibial inserts (all variants (CR, PS and UC) of modular meniscal insert and all-poly tibial baseplate components) to Vitamin-E Stabilized, 100 kGy crosslinked UHMWPE (Vit-E HXLPE). This 510(k) also notifies the FDA of minor design updates to the implants and reusable instruments.

Materials: Wrought Cobalt-28Chromium-6Molybdenum Alloy (ASTM F1537-11) for the femoral component, Wrought Titanium-6Aluminium-4Vanadium ELI Alloy (Ti6Al4V ELI, ASTM F136-13) for the tibial baseplate components, Ultra-High-Molecular-Weight Polyethylene (UHMWPE) for all variants of the patellar implants, Ultra-High-Molecular-Weight Polyethylene (UHMWPE) **or** Vit-E HXLPE for the All-poly tibial baseplate components and modular meniscal tibial inserts.

Indications for Use:

The patient should be skeletally mature to receive a knee replacement. Patients should have adequate bone stock and size to support and accept the prosthesis.

The patient's need for knee replacement should be due to one or more of the following conditions:

- Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis.
- Inflammatory degenerative joint disease including rheumatoid arthritis.
- Functional deformity such as varus, valgus or flexion deformities.
- Revision procedures where other treatments or devices have failed.
- Fractures that are unmanageable using other techniques.

Signature Orthopaedic's World Knee replacement components may be intended for cemented or cementless use. Please verify whether the particular component is intended for cemented or cementless use by checking the package label.

Intended Use:

The World Knee Total Knee System's intended use is for total knee replacement procedures in skeletally mature patients with structural joint damage. This is the same intended use as previously cleared for the World Knee Total Knee System, K190557 and K181530.

Comparison of Technological Characteristics:

The World Knee Total Knee System described in this Special 510(k) Device Modification is fundamentally the same device as the primary predicate device cleared

in K190577 and K181530. The technological characteristics that remain the same for the World Knee Total Knee System are as follows:

- Clinical Indications for Use, Intended Use and Surgical Techniques for the World Knee Variant and the World Knee Total Knee System are identical.
- The main components of the World Knee Variant use the same materials during the manufacturing process. This includes:
  - Wrought Cobalt-28Chromium-6Molybdenum Alloy (ASTM F1537-11) for the femoral component,
  - Wrought Titanium-6Aluminium-4Vanadium ELI Alloy (Ti6Al4V ELI, ASTM F136-13) for the tibial baseplate components,
  - Ultra-High-Molecular-Weight Polyethylene (UHMWPE) for all variants of the patellar implant,
  - Ultra-High-Molecular-Weight Polyethylene (UHMWPE) option for All-poly tibial baseplates and modular meniscal tibial inserts.
- The manufacturing process of the World Knee Variant in question has the same manufacturing process as the World Knee Total Knee System. This includes cleaning and passivation, packaging, transportation and sterilisation.
- The World Knee Variant has the same geometry and fundamental design as the World Knee Total Knee System. All interconnections between components are the same.
- All implants are provided sterile with SAL of 10^{-6} as seen in the World Knee Total Knee System.
- The World Knee Variant has the same body contact as the World Knee Total Knee System and as such has the same contact stresses

The primary differences between the subject and primary predicate World Knee devices are as follows:

- Vitamin-E Stabilized and 100 kGy crosslinked UHMWPE (Vit-E HXLPE) material was added as an option for manufacturing of the tibial inserts (All-poly tibial baseplate components and modular meniscal tibial insert); and
- Updates to the reusable instruments were made to facilitate surgery and improve usability.

Performance Testing:

Engineering evaluations were conducted to verify that the performance of the World Knee with Vitamin-E Poly Tibial Insert variants is equal to and/or better than the predicate device and therefore adequate for anticipated in-vivo use. The following V&V activities were conducted:

- V&V of substantial equivalence and/or superiority of performance characteristics and material properties of the Vit-E HXLPE relative to the standard UHMWPE for the:
  - Density as per ASTM F648 and D792;
  - Mechanical Properties as per ASTM F648, F2759, D695 and F2183;
  - Melting Point, Crystallinity and Enthalpy of Fusion as per ASTM F2635l;

  - Swell Ratio and Crosslink Density as per ASTM F2214;
  - Fatigue Crack Propagation and Coefficient as per ASTM E647;
  - Oxidation Challenge as per ASTM F2003 and analysis as per ASTM F2102 (both 2 and 6-weeks accelerated aging);
  - ESR Testing for residual free radical content and Transvinylene Index (TVI) as per ASTM F2381; and
  - Resistance to wear for 5 million cycles as per ISO 14243 Part 1 and 2.
- Verification of substantial equivalence of the mechanical integrity of the Vit-E HXLPE tibial insert components including the baseplate locking mechanism relative to the standard UHMWPE tibial insert.
- Risk Analysis and Design Control Review found no new or changed risks relative to the Indications for Use and Efficacy of the Subject Device.

Substantial Equivalence Conclusion:
The results of the V&V testing, associated engineering review, risk analysis and design control activities demonstrated substantial equivalence of the subject World Knee Total Knee System to the primary predicate cited herein.