November 4, 2022

Signature Orthopaedics Pty Ltd.
Declan Brazil
Managing Director
7 Sirius Road
Lane Cove, NSW 2113
AUSTRALIA

Re: K223062
Trade/Device Name: World 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
Dated: September 20, 2022
Received: September 30, 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 -S

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)*

K223062

Device Name
World 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.

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 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: September 16th, 2022

Classification: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (JWH, 21CFR 888.3560)

Predicate Devices:

Primary Predicate

- Signature Orthopaedics World Knee Total Knee System (K181530)

Additional Predicate

- Signature Orthopaedics World Knee Total Knee System (K190577)
- OMNI TiN Coated Apex Knee System (K191765)

Device Description:

The World 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 tibial baseplate components are intended for use with or without bone cement. The femoral component, meniscal inserts and all polyethylene

tibias are available as posterior stabilised or cruciate retaining variants. The femoral components are also available as anatomic asymmetrical and symmetrical design variants. The femoral component may be used with modular pegs.

The primary purpose of this Special 510(k) Device Modification to the World Knee System is to notify the FDA of the addition of titanium nitride (TiN) material coating to the femoral components (posterior stabilised{PS}, cruciate retaining{CR}) of the cemented variant. This 510(k) also notifies the FDA of minor design update to the femoral component implant.

Materials: Cast Cobalt Chromium (CoCr) alloy **(**ASTM F75 and ISO 5832-4) for the femoral component and tibial baseplate, Wrought Titanium-6Aluminium-4Vanadium ELI Alloy (Ti6Al4V ELI, ASTM F136-13) for the femoral peg component and tibial baseplate variant, 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, and titanium nitride (TiN) for coating cemented femoral components.

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

Comparison of Technological Characteristics:

The World Total Knee System described in this Special 510(k) Device Modification is essentially the same device as the primary predicate device cleared in K181530. The technological characteristics that remain the same for the World Total Knee System are as follows:

- Clinical Indications for Use, Intended Use and Surgical Techniques for the World Knee variant and the World Total Knee System are identical.
- The main components of the World Total Knee System use the same materials during the manufacturing process. This includes:
  - Cast Cobalt Chromium Alloy (ASTM F75 and ISO 5832-4) for the femoral component,
  - Wrought Titanium-6Aluminium-4Vanadium ELI Alloy (Ti6Al4V EELI, ASTM F136-13) for the femoral peg and 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.
- Processes including cleaning, passivation, packaging, sterilisation and transport are the same as the World Total Knee System processes.
- The World Knee variant has the same geometry and fundamental design as the World Total Knee system component. All interconnections between components are the same.
- The World Knee variant has the same body contact as the World Total Knee System and as such has the same contact stresses.
- All implants are provided sterile with SAL of 10^{-6} as seen in the World Total Knee System.

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

- Titanium nitride (TiN) coating was added as an option for the femoral components (PS and CR) of the cemented variant only; and
- The manufacturing process for the World Total Knee femoral component variant in question includes an additional step of TiN coating applied by Physical Vapor Deposition (PVD) method. The TiN coating is applied to fully machined parts.
- Minor design change limited to the largest size of asymmetrical variant of the femoral component in accordance with the device intended use and function.

Note that for all other implants of the World Total Knee System described in this 510(k) notification, there are no changes in the manufacturing processes in comparison to the predicate devices K181530, K190577 and K191765.

Performance Testing:

Engineering evaluations were conducted to verify that the performance of the World Knee TiN coated femoral components is equal to and/or better than the predicate device and therefore adequate for the anticipated in-vivo use. The following V&V activities were conducted:

- Cytotoxicity testing of TiN coating on CoCr alloy implant as per ANSI/AAMI/ISO 10993-5
- Bioburden testing of TiN coated CoCr alloy implant as per ANSI/AAMI/ISO 11737-1:2018
- Verification of substantial equivalence of coating pullout strength of the TiN coating on CoCr alloy components.
- Wear testing for 5 million cycles was done in accordance with ISO 14243-

1:2009 and reported in master file MAF 1413 of the TiN coating applied by PVD method to the subject device.

- An overlay of the largest size femoral component of asymmetrical and symmetrical variants showed that the edge radii of both components were matching, hence the geometry of the updated design change is the same as predicate devices.
- Risk Analysis and Design Control Review found no new or changed risks relative to the Indications for Use and efficacy of the Subject Device.
- The addition of TiN coating on CoCr alloy implants was verified by Signature Orthopaedics by reviewing the list of contents of MAF1413 for Medthin 01 TiN provided by IHI Ionbond AG.

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 Total Knee System to the primary predicate cited herein.