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

October 24, 2018

Re: K181530
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, MBH
Dated: September 19, 2018
Received: September 24, 2018

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/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
2018.10.24 20:21:31 -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)*
K181530

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 Orthopaedics' 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 2 510(K) SUMMARY

**Manufacturer:**
Signature Orthopaedics Pty Ltd
7 Sirius Road
Lane Cove, NSW 2066
Australia

**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:** June 08th, 2018

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

Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis (MBH, 21CFR 888.3565)

**Predicate Devices:**
Substantial equivalence to the following device is claimed:

- Signature Orthopaedics World Knee System (K180750)
- Signature Orthopaedics Genius Knee System (K170613)
- DJO Surgical 3D Knee (K020114, K032905)
- Total Joint Orthopedics Klassic Knee System (K112906, K162422, K180159)
- Smith & Nephew Genesis II Knee System (K951987, K032683, K030612)

**Device Description:**

The World 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 manufactured from cast cobalt chromium alloy and are intended for use with or without bone cement. The cementless variants are additionally coated with cobalt chromium beads and hydroxyapatite.
The cemented femoral components are also available as a symmetrical variant.
The femoral component may be used with modular pegs. The modular femoral peg is

manufactured from wrought cobalt chromium alloy. The femoral component, meniscal inserts and all polyethylene tibias are available as postererior stabilized or cruciate retaining variants.
Cruciate retaining meniscal inserts are available as standard or ultracongruent designs.
All variants of the all polyethylene tibia, meniscal insert and patella are manufactured from UHMWPE. The patella components are available in a spherical or non-symmetrical designs.

**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 Orthopaedics' 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.

**Performance Testing:**

Non-clinical testing and engineering evaluations were conducted to verify that the performance of the World Knee system is adequate for anticipated in-vivo use. Non-clinical testing or engineering analysis carried out on the World Knee system included:

- Range of motion analysis
- Component contact area and stress testing
- Porous coating characterization, shear strength, tensile strength and shear fatigue testing

**Substantial Equivalence:**

Signature Orthopaedics believes that Signature World Knee Total Knee Replacement System is substantially equivalent to Signature Orthopaedics World Knee System (K180750), Signature Orthopaedics Genius Knee System (K170613), DJO Surgical3DKnee (K020114, K032905), Total Joint Orthopaedics Klassic Knee System (K112906, K162422, K180159) and Smith & Nephew Genesis II Knee System (K951987, K032683, K030612). Non-clinical testing results support the substantial equivalence claim. The subject devices are expected to perform adequately during

clinical use.

**Comparison of technological characteristics**

The World Knee System shares the same intended use and indications for use as the predicates devices. The materials are the same as the Signature Orthopaedics World Knee System (K180750), Signature Orthopaedics Genius Knee System (K170613) and Total Joint Orthopedics Klassic Knee System (K112906, K162422, K180159). The Symmetrical World Knee femur's geometry is similar to the Total Joint Orthopedics Klassic Knee System. The World Knee All Poly Tibia is similar in geometry to the Smith & Nephew Genesis II Knee System's All Poly Tibia (K951987, K032683, K030612). The World Knee patellas are similar in geometry to the Signature Orthopaedics World Knee System, Signature Orthopaedics Genius Knee System and Smith & Nephew Genesis II Knee System's patellas.