November 27, 2019

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

Re: K190577
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
Dated: October 24, 2019
Received: October 28, 2019

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,

For Ting Song, Ph.D.
Acting 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

1 INDICATIONS FOR USE STATEMENT

Device Name: World Knee Total Knee System

Indications for Use:
The patient should be skeletally mature to receive a World Knee replacement system. 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.

The World Knee replacement system is indicated for cemented fixation with bone cement (PMMA) only.

Prescription Use: Yes (Part 29 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use: No (Part 29 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Signature Orthopaedics Pty Ltd

2 510(K) SUMMARY

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

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: November 26th, 2019

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)

Predicate Devices:

Primary Predicate:

- Signature Orthopaedics World Total Knee System (K180750 & K181530)
- Signature Orthopaedics Genius Total Knee System (K170613)

Secondary Predicates:

- Signature Orthopaedics Active-X Knee System (K160159)
- Smith & Nephew Genesis II Total Knee System (K030612 & K032683)

Reference Predicate:

- Signature Orthopaedics Pegasus Stem (K133370)

Device Description:

Devices covered in this 510(K) are a range extension to previously cleared 510(K) applications for World Knee system. The range extension consists of titanium tibial

baseplates for the World knee, and a change to the meniscal insert connection mechanism for the World knee. The tibial baseplate is made of Titanium available in cemented version. The World Knee meniscal inserts are available as posterior stabilized or cruciate retaining variants. Cruciate retaining meniscal inserts are available as standard or ultracongruent designs. All variants of the meniscal inserts are manufactured from UHMWPE.

Indications for Use:

The patient should be skeletally mature to receive a World Knee replacement system. 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.

The World Knee replacement system is indicated for cemented fixation with bone cement (PMMA) only.

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 carried out on the World Knee system included:

- Modular component interlock strength testing per ASTM F1814
- Modular component assembly testing per ASTM F1814
- Tibial plate fatigue strength testing per ASTM F1800
- Endotoxin testing per AAMI ST72

Substantial Equivalence:

The Signature Orthopaedics World Knee System has the same intended use, indications for use, materials and similar design features to the predicate devices. Non-clinical testing results support the substantial equivalence claim.

Comparison of technological characteristics

The World Knee System design is similar to Signature Orthopaedics World Knee Systems (K180750 & K181530). The World Knee tibial plate material is similar to Smith & Nephew Genesis II Total Knee System (K030612 & K032683). The World Knee Meniscal insert material is the same as Signature Orthopaedics Genius Knee System (K170613), Signature Orthopaedics Active-X Knee System (K160159) and Smith & Nephew Genesis II Total Knee System (K030612 & K032683).

Signature Orthopaedics Pty Ltd

Conclusions:

Technical comparison of the subject and predicate devices demonstrates equivalence in device design, intended use, indications for use and material. Non-clinical data support the safety and effectiveness of the Signature Orthopaedics World Knee Total Knee System.