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

April 20, 2018

Re: K180750
Trade/Device Name: World 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: March 15, 2018
Received: March 22, 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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Katherine D. Kavlock -S

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)*
K180750

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

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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Signature Orthopaedics Pty Ltd

510(K) SUMMARY

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

Device Trade Name: World 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: January 12th, 2018

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

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

- Signature Orthopaedics Genius Total Knee System (K170613)

Device Description:

The World Knee system is a modular knee system consisting of a femoral component, meniscal insert, a patella and a tibial baseplate. The femoral component and tibial baseplate components are manufactured from cast cobalt chromium alloy and are intended for use with bone cement. The modular femoral peg is manufactured from wrought cobalt chromium alloy. The femoral component and meniscal inserts are available as posterior stabilised or cruciate retaining variants. Cruciate retaining meniscal inserts are available as standard or ultracongruent designs. All variants of the meniscal insert and patella are manufactured from UHMWPE.

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.

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

Performance Testing:

Engineering evaluations were conducted to verify that the performance of the World Knee system is is equal or better than the predicate device and therefore adequate for anticipated in-vivo use.

Substantial Equivalence:

The World Knee System has the same intended use, indications for use, materials and similar design as the Signature Orthopaedics Genius Knee System (K170613). The subject devices are expected to perform adequately during clinical use.

Comparison of technological characteristics

The following technological similarities exist between the subject and predicate devices:

- the World Knee incorporates the same materials as the Genius Knee
- the World Knee has the same manufacturing process as the Genius Knee
- the World Knee has the same geometry and fundamental design as the Genius Knee
- the World Knee has the same body contact as the Genius Knee
- the World Knee has the same sterilization process as the Genius Knee

The following technological differences exist between the subject and predicate devices:

- there are minor design differences in the femoral components, and meniscal insert component
- an additional 2 intermediate sizes have been added