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

September 21, 2020

Re: K201278
Trade/Device Name: World Hip Stem, World Cup, World Liner
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MEH, LPH, KWZ
Dated: August 31, 2020
Received: September 4, 2020

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,

Vesa Vuniqi, M.S.
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

510(k) Number (if Known): K201278

Device Name: World™ Hip System

Indications For Use:

Components of the Signature Orthopaedics hip replacement range are intended to replace a hip joint where bone stock is sufficient to support the implant. When a surgeon has selected prosthetic replacement as the preferred treatment, the devices are indicated for:

- Non-inflammatory degenerative joint disease including osteoarthritis or avascular necrosis
- Inflammatory joint disease including rheumatoid arthritis
- Correction of functional deformity including congenital hip dysplasia
- Traumatic injury involving the hip joint including traumatic arthritis or femoral head or neck fracture
- Failed previous hip surgery including internal fixation or joint fusion, reconstruction, hemiarthroplasty, surface replacement, or total replacement

Signature Orthopaedics' Origin, Aria, Remedy, TSI, Pegasus, Spartan, and World Hip femoral stems, SignaSure Cementless Cups, Logical and World Acetabular Cups are intended for cementless fixation only.
Signature Orthopaedics' Evolve, Cemented TSI (both CoCr and HNSS variants) and Cemented Origin femoral stems and SignaSure Cemented Cups are intended for cemented fixation only.
Signature Orthopaedics' SignaSure Insert is indicated for use with a cementless Signature Orthopaedics' Logical Acetabular Cup to provide dual mobility articulation.
Signature Orthopaedics' constrained liner components are indicated particularly for patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability.
Signature Orthopaedics' Evolve UniPolar Head and BiPolar Head are intended for hemi-hip arthroplasty only, where the natural acetabulum does not require replacement. The Evolve UniPolar Head and BiPolar Head are indicated for bone fractures or pathologies involving only the femoral head/neck and/or proximal femur, such as:

- Acute femoral head or neck fracture
- Fracture dislocation of the hip
- Avascular necrosis of the femoral head
- Non-union of femoral neck fractures
- Certain high subcapital and femoral neck fractures in the elderly
- Degenerative arthritis involving only the femoral head
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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)

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™ Hip System

Common Name:

Cementless Hip Replacement 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:

8th of May 2020

Classification:

Class II per 21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. (MEH)

Class II per 21 CFR 888.3358: Hip joint metal/polymer/metal

semi-constrained porous-coated uncemented prosthesis (LPH)

Class II per 21 CFR 888.3310: Hip joint metal/polymer constrained, cemented or uncemented prosthesis (KWZ)

Predicate Devices:

Primary Predicate

- Signature Orthopaedics Logical G-Series Acetabular Cup and Liner (K121297)

Reference Predicate

- Zimmer Wagner Cone Prosthesis® Hip Stem (K113556)
- Signature Orthopaedics Logical XLPE 20° Hooded Liner (K153131)

Additional Predicate

- Signature Orthopaedics Pegasus Stem (K133370)
- Smith & Nephew's R3 Acetabular Cup (K061253)

Device Description:

Signature Orthopaedics' World™ Hip Stem is a circular tapered stem with longitudinal ribs intended for single use and cementless fixation in total hip arthroplasty. The stem is manufactured from forged Ti6Al4V alloy as per ASTM F136. It features a grit blasted body and a 12/14 taper connection with the trunnion surface roughness as Rz 2.5, which allows for compatibility with Signature Orthopaedics' range of previously cleared femoral head components.

Signature Orthopaedics' World™ Acetabular Cups are metal backed cementless acetabular cups with highly cross-linked polyethylene liner intended for use in total hip arthroplasty. The shells are available in a three hole configuration, which allows use of supplemental bone screws for supplemental fixation. The World™ Acetabular Cups are compatible with World™ Liners.

Signature Orthopaedics' World™ Liners are designed to articulate with a femoral head of appropriate diameter. The liners are available in neutral, 10° hooded and 20° hooded, allowing the option to address potential joint stability concerns.

Indications for Use:

Components of the Signature Orthopaedics hip replacement range are intended to replace a hip joint where bone stock is sufficient to support the implant. When a surgeon has selected prosthetic replacement as the preferred treatment, the devices are indicated for:

- Non-inflammatory degenerative joint disease including osteoarthritis or avascular necrosis
- Inflammatory joint disease including rheumatoid arthritis
- Correction of functional deformity including congenital hip dysplasia
- Traumatic injury involving the hip joint including traumatic arthritis or femoral head or neck fracture
- Failed previous hip surgery including internal fixation or joint fusion, reconstruction, hemiarthroplasty, surface replacement, or total replacement

Signature Orthopaedics' Origin, Aria, Remedy, TSI, Pegasus, Spartan, and World™ Hip femoral stems, SignaSure Cementless Cups, Logical and World™ Acetabular Cups are intended for cementless fixation only.

Signature Orthopaedics' Evolve, Cemented TSI (both CoCr and HNSS variants) and Cemented Origin femoral stems and SignaSure Cemented Cups are intended for cemented fixation only.

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The Evolve UniPolar Head and BiPolar Head are indicated for bone fractures or pathologies involving only the femoral head/neck and/or proximal femur, such as:

- Acute femoral head or neck fracture
- Fracture dislocation of the hip
- Avascular necrosis of the femoral head
- Non-union of femoral neck fractures
- Certain high subcapital and femoral neck fractures in the elderly
- Degenerative arthritis involving only the femoral head

Summary of Technological Characteristics:

The subject devices share the same characteristics and the predicate devices as follows:

- The World™ Hip System is intended for cementless fixation which is the same intended use as one or more of the predicate devices.
- The World™ Hip System has the same indications for use as the predicate devices.
- The World™ Hip System has the same manufacturing route as the predicate devices.
- The World™ Hip System is manufactured from the same materials as the predicate devices.
- The World™ Hip System has the same body contact as the predicate devices.
- The World™ Stem's taper connection is identical to Signature Orthopaedics' Pegasus Stem.
- The World™ Acetabular Cup has the same coating as Signature Orthopaedics' Logical G-Series Acetabular Shell.
- The World™ Hip System has the same shelf life as Signature Orthopaedics' Pegasus Stem, Logical G-Series Acetabular Cup and Liner, and Logical XLPE Liners.
- The World™ Hip System has the same sterilization process as Signature Orthopaedics' Pegasus Stem, Logical G-Series Acetabular Cup and Liner, and Logical XLPE Liners.

The following are the technological differences between the World™ Hip System and its predicate devices:

- Some of the World™ Hip System's design features differ from the predicate devices.
- The World™ Stem's trunnion surface finish differs from Signature Orthopaedics' Pegasus Stem.

Performance Testing:

Non-clinical testing and engineering evaluations were conducted to verify that the performance of the World™ Hip System are adequate for anticipated in-vivo use. Non-clinical testing carried out included:

- Range of motion testing as per ISO 21535
- Stem fatigue testing as per ISO 7206-4
- Neck fatigue testing as per ISO 7206-6

- Head disassembly testing as per ISO 7206-10
- Head rotational stability testing as per ISO 7206-13
- Head static burst testing as per ISO 7206-10
- Head fatigue and static burst test post fatigue testing
- Fretting corrosion testing
- Shell stiffness testing
- Shell and liner range of motion testing
- Articular surface wear testing
- Liner-shell assembly/disassembly testing
- Liner-shell torsion testing
- Liner lever out testing
- Liner impingement testing

Substantial Equivalence Conclusion:
Signature Orthopaedics' World™ Hip System has the same intended use, indications for use, material and similar design features as Zimmer Wagner Cone Prosthesis® Hip Stem (K113556), Signature Orthopaedics Pegasus Stem (K133370), Signature Orthopaedics Logical G-Series Acetabular Cup and Liner (K121297), Signature Orthopaedics Logical XLPE 20° Hooded Liner (K153131), Smith & Nephew's R3 Acetabular Cup (K061253) and non-clinical testing support the substantial equivalence claim.