January 7, 2022

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

Re: K211742
Trade/Device Name: SignaSure Dual Mobility System
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, LZO
Dated: December 20, 2021
Received: December 23, 2021

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,

Limin Sun, 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

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)*
K211742

Device Name
SignaSure Dual Mobility System

Indications for Use *(Describe)*
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, World and Encore 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 the 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

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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2 510(K) SUMMARY

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

Device Trade Name:
SignaSure Dual Mobility System

Common Name:
Hip Replacement Prosthesis

Contact:
Dr. Declan Brazil

CEO 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 4th, 2021

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 888.3353: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented (LZO)

Predicate Devices:

Primary Predicate

- Serf Novae Dual Mobility Acetabular Cup (K111572)
- Serf CI../..X liner for Novae Dual Mobility Acetabular Cup (K142675)
- Stryker Restoration Anatomic Dual Mobility (ADM) System (K072020, K093644)

Reference Predicate

- Signature Orthopaedics Logical C-Series Cup (K153131)
- Signature Orthopaedics Logical XLPE Liner (K121297)
- Signature Orthopaedics CoCr Femoral Head (K121297)

Device Description:

The SignaSure Dual Mobility System consists of cementless and cemented shells, and a poly component. The SignaSure Poly is manufactured from crosslinked polyethylene and is spherical in geometry with outer and inner spherical conforming articular surfaces. The inner articular surface mates and retains a femoral head. The outer articular surface

articulates within the highly polished inner diameter of the SignaSure Cementless or Cemented Cup. The SignaSure Cementless Cup is manufactured from CoCr alloy and is sequentially plasma sprayed with titanium coating and hydroxyapatite to gain cementless fixation. The SignaSure Cemented Cup is manufactured from CoCr alloy and is grit blasted and macro textured to aid in fixation via bone cement.

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, World and Encore 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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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.

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- 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

Performance Testing:

Non-clinical testing and engineering evaluations were conducted to verify that the performance of the SignaSure Dual Mobility System is adequate for anticipated in-vivo use. The following non-clinical testings was carried out:

- Head assembly/disassembly/lever out testing

- Range of motion analysis
- Coating adhesion
- Articular surface wear
- Impingement testing
- Post impingement lever out testing

Substantial Equivalence:

The Signature Orthopaedics SignaSure Dual Mobility 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 SignaSure Dual Mobility System shares the same intended use and indications for use as the predicates devices. The materials are the same as the Stryker ADM Cup (K072020, K093644), and Logical XLPE Liner (K121297). The SignaSure Cup's geometry is similar to the Serf Novae Dual Mobility Acetabular Cup (K111572). The SignaSure Cementless Cup's coating is identical to the Logical C-Series Cup (K121297). The SignaSure Cemented Cup's outer surface is similar to the Serf Novae Stick Dual Mobility Acetabular Cup (K111572).

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 of the Signature Orthopaedics SignaSure Dual Mobility System.