January 13, 2023

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

Re: K220495
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 8, 2022
Received: December 14, 2022

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 -S

Limin Sun, Ph.D.
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K220495

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
- Dislocation risks (when used with SignaSure range)

Signature Orthopaedics' Origin, Aria, Remedy, Origin-NS, Pegasus, Spartan, World and Everglade 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 Logical/World Metal Insert is indicated for use with a cementless Signature Orthopaedics' Logical/World 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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# 510(K) SUMMARY - SIGNASURE DUAL MOBILITY SYSTEM

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

**Additional Manufacturer:**
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**Contact:**
Dr. Declan Brazil
CEO of Signature Orthopaedics

**Prepared By:**
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Australia
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**Date Prepared:** April 20th, 2022

**Device Trade Name:** SignaSure Dual Mobility System

**Common Name:** Hip Replacement Prosthesis

**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**

- Stryker Modular Dual Mobility (MDM) Insert and Polyethylene (K103233, K112556)

**Additional Predicates**

- 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)
- Signature Orthopaedics SignaSure Dual Mobility System (K211742)

**Reference Predicate**

- Signature Orthopaedics Logical C-Series Cup (K153131)
- Signature Orthopaedics Logical XLPE Liner (K121297)
- Signature Orthopaedics CoCr Femoral Head (K121297)
- Biomet G7 Dual Mobility System (K150522)

**Device Description:**

The SignaSure Dual Mobility System is available in two configurations, a Monobloc configuration and a Modular configuration. The Monobloc configuration is a Dual Mobility acetabular system consisting of a metallic shell, cementless or cemented, and a mobile polyethylene insert to articulate within the shell as well as a femoral head. The Modular configuration (subject device) is a dual mobility acetabular system consisting of 2 components; a mobile polyethylene component and a metallic insert which can be used with interfacing cemented or cementless cups.

The SignaSure Poly, used in both configurations, is manufactured from highly crosslinked polyethylene (as per ASTM F648) 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 to be used, or the metallic insert. The SignaSure Poly components are available in size 37 to 41 mm (outer diameter) allowing use with 22 mm and 39 to 59 mm femoral heads.

The SignaSure Logical Insert is manufactured from Cobalt Chrome (CoCr) alloy (as per ASTM F1537 and ISO 5832-12) and mates with Signature Orthopaedics' Logical Shell to be implanted without bone cement and the SignaSure World Insert is manufactured from CoCr alloy (as per ASTM F1537 and ISO 5832-12) and mates with Signature Orthopaedic's World Cup to be implant without bone cement. The SignaSure Logical Insert is available in 34 to 48 mm sizes whereas the SignaSure World Insert is available in 38 to 46 mm (internal diameter) sizes.

The SignaSure Cementless Cup is manufactured from CoCr alloy (as per ASTM F1537 and ISO 5832-12) and is sequentially plasma sprayed with titanium coating (as per ASTM F1580) and hydroxyapatite (as per ISO 13779-1 and ISO 13779-2) to gain cementless fixation. The SignaSure Cemented Cup is manufactured from CoCr alloy (as per ASTM F1537 and ISO 5832-12) and is grit blasted and macro textured to aid in fixation via bone cement. These cups, as from K211742, underwent no changes and were included in this submission as they interact with the subject SignaSure Poly devices.

**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
- Dislocation risks (when used with SignaSure range)

Signature Orthopaedics' Origin, Aria, Remedy, Origin-NS, Pegasus, Spartan, World and Everglade 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 Logical/World Metal Insert is indicated for use with a cementless Signature Orthopaedics' Logical/World 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

**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 tests were carried out:

- Liner-Shell Offset Pull-Out Strength per ASTM F1820
- Liner-Shell Rotational Stability (torque-out) per ASTM F1820
- Liner-Shell Push-Out Strength per ASTM F1820
- Fretting Corrosion as per ASTM F1875 and Engineering Evaluation
- Impingement per ASTM F2582-14
- Range of Motion Testing per ISO 21535:2007
- Head Poly Assembly Testing
- Head Poly Pull-Out Testing
- Head Lever Out Testing
- Post Impingement Lever-Out Testing per ASTM F1820

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

<u>SignaSure Dual Mobility System (Modular Insert configuration):</u>

- The SignaSure Modular Insert Dual Mobility System shares the same intended use and indications for use as Stryker's MDM Insert (K103233, K112556).
- The SignaSure Poly material is the same as Stryker's MDM Insert (K103233, K112556).
- The SignaSure Insert material is the same as Stryker's MDM Insert (K103233, K112556).

SignaSure Dual Mobility System (Monobloc configuration):
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).

The SignaSure Dual Mobility System's Monobloc Configuration is unchanged when compared to the Monobloc Configuration cleared in K211742.

**Conclusions:**
Technical comparison, engineering evaluation, and review of the documentation provided for the subject and predicate devices demonstrates substantial equivalence in device design, intended use, indications for use and material. Non-clinical data supports the safety and effectiveness of the Signature Orthopaedics SignaSure Dual Mobility System.