August 1, 2024

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

Re: K241690
Trade/Device Name: Logical Liner; World Liner; World Knee Patella
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, JWH, MBH
Dated: July 29, 2024
Received: July 29, 2024

Dear Dr. 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241690

Device Name
Logical Cup;
World Acetabular Cup;

Indications for Use:

Logical Liner and World Liner

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 intended 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

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
241690

Device Name
World Knee System

Indications for Use *(Describe)*
Patients 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.

Signature Orthopaedics' World Knee replacement components may be intended for cemented or cementless use.

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)

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510(k) SUMMARY

Manufacturer:	Signature Orthopaedics Pty Ltd 7 Sirius Road Lane Cove, NSW 2066 Australia
Device Trade Name:	Logical Liner, World Liner, World Knee Patella
Common Name:	Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calcium Phosphate (MEH) Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented (LPH) Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer (JWH) Prosthesis, Knee, patello/femorotibial, semi-constrained, uncemented, porous, coated, polymer/metal/polymer (MBH)
Contact:	Dr. Declan Brazil Managing Director, Signature Orthopaedics Pty Ltd
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:	July 26th, 2024
Classification:	Class II per 21 CFR 888.3353: Hip joint metal/ceramic/ polymer semi-constrained cemented or nonporous uncemented prosthesis Class II per 21 CFR 888.3560: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Predicate Devices:	Substantial equivalence to the following devices is claimed, • Signature Orthopaedics Logical Acetabular (K153131) – Primary Predicate • Signature Orthopaedics Logical Acetabular (K121297) • Signature Orthopaedics World Liner (K201278) • Signature Orthopaedics World Knee System (K180750 and K181530) • InSitu Total Hip System (NextStep Arthropedix, K192071)

Device Description:

The primary purpose of this Special 510(k) Device Modification to devices cleared as part of the Logical Cup, World Hip, and World Knee System, is to notify the FDA of the the change in materials used to manufacture the polyethylene components (Logical Liner, World Liners and World Knee Patella) to Vitamin-E Stabilized, 100 kGy crosslinked UHMWPE (Vit-E HXLPE) that is the subject of Masterfile MAF 2795. This 510(k) also notifies the FDA of minor design updates to the implants and reusable instruments.

The Logical Acetabular System consists of an Acetabular Shell and a highly cross-linked polyethylene Acetabular Liner that is available in neutral, hooded and lateralized variants. The liner is designed to sit within an acetabular shell and articulate with a femoral head.

The World Liners are compatible with World Acetabular Cups and are available in neutral, and hooded variants. The liners are designed to sit within an acetabular shell and articulate with a femoral head.

The World Knee Patella is available in symmetrical and asymmetrical variants, with pegs. It is part of the World Knee System, which is a modular knee system consisting of a femoral component, meniscal inert, a patella and a tibial component.

Indications for Use:

Logical Liner and World Liner

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 intended 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

World Knee System

Patients 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.

Signature Orthopaedics' World Knee replacement components may be intended for cemented or cementless use.

Intended Use:

The intended use for the Logical Acetabular, World Liner and World Knee System are identical to their previously cleared predicate devices (K121297, K153131. K201278, K180750 and K181530).

Components of the Signature Orthopaedics hip replacement range (Logical Acetabular and World Hip) are intended to replace a hip joint where bone stock is sufficient to support the implant.

The World Knee Total Knee System's intended use is for total knee replacement procedures in skeletally mature patients with structural joint damage.

Comparison of Technological Characteristics:

The Logical Acetabular, World Hip and World Knee System described in this Special 510(k) Device Modification are essentially the same device as the respective primary predicate devices cleared in K121297, K153131, K201278, K180750 and K181530. The technological characteristics that remain the same for the subject device systems are as follows:

- Indications for Use, Intended Use and Surgical Techniques for the Vit-E HXLPE Variants and the previously cleared UHMWPE components are identical except changes to the polyethylene materials.
- The manufacturing process of the Vit-E HXLPE Variants have the same manufacturing processes as the previously cleared systems. This includes cleaning and passivation, packaging, transportation, and sterilization.
- The Vit-E HXLPE Variants have the same geometry and fundamental design as the previously cleared predicate devices. All interconnections between components are the same.
- All implants are provided sterile with SAL of 10^{-6} as seen in the predicate systems.
- The Vit-E HXLPE Variants have the same body contacts as previously cleared systems, and as such have the same contact stresses.

The primary differences between the subject and primary predicate devices are as follows:

- Vitamin-E Stabilised and 100kGy crosslinked UHMWPE (Vit-E HXLPE) material was added as an option for manufacturing of the Logical Liners, World Liners, and World Knee Patella; and
- Updates to implant and reusable instrument components to improve usability and/or functionality, and facilitate surgery.

Performance Testing:

Engineering evaluations were conducted to verify that the performance of the Logical Acetabular, World Hip and World Knee systems with Vit-E HXLPE variants are equal to and/or better than the predicate devices and therefore adequate for anticipated clinical use. The following V&V activities were conducted:

- V&V of substantial equivalence of material properties of the Vit-E HXLPE relative to the predicates:
    - Density as per ASTM F648 and D792;

  - Mechanical Properties as per ASTM F648, F2759, D695 and F2183;
  - Melting Point, Crystallinity and Enthalpy of Fusion as per ASTMF26351;
  - Swell Ratio and Crosslink Density as per ASTM F2214;
  - Fatigue Crack Propagation and Coefficient as per ASTM E647;
  - Oxidation Challenge as per ASTM F2003 and analysis as per ASTM F2012 (both 2 and 6-weeks accelerated aging);
  - ESR Testing for residual free radical content and Transvinylene Index (TVI) as per ASTM F2381; and
  - Resistant to wear for 5 million cycles as per ISO 14243 Part 1 and 2.
- Wear and impingement assessment
- Verification of substantial equivalence of the mechanical integrity of the Vit-E HXLPE components including any locking mechanisms relative to the standard UHMWPE components.
- Risk Analysis and Design Control Review found no new or changed risks

Substantial Equivalence:

The results of the V&V testing, associated engineering review, risk analysis and design control activities demonstrated substantial equivalence of the subject device systems to their primary predicates cited herein.