August 7, 2025

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

Re: K243021
Trade/Device Name: Longboard Revision Hip Stem
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: LZO, KWZ, KWL, KWY, LPH, OQI
Dated: July 21, 2025
Received: July 21, 2025

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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)*
K243021

Device Name
Longboard Revision Hip Stem

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 & fracture non-union or mal-union
- 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, hemiarthroplasty, surface replacement, or total hip replacement
- Dislocation risks (when used with SignaSure Dual Mobility System)

Signature Orthopaedics' Longboard Revision Stem is intended for individuals undergoing revision surgery of the hip only.

Signature Orthopaedics' Origin, Origin TT, Aria, Remedy, Origin-NS, Pegasus, Spartan, World, Everglade and Longboard Hip femoral stems, SignaSure Cementless Cups, Logical and World Acetabular Cups are intended for cementless fixation 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.

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.

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510(k) SUMMARY

Manufacturer:	Signature Orthopaedics Pty Ltd 7 Sirius Road Lane Cove, NSW 2066 Australia
Device Trade Name:	Longboard Revision Hip Stem
Common Name:	Femoral Hip 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:	Aug 7th, 2025
Classification:	Class II per 21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (LZO) Class II per 21 CFR 888.3310: Hip joint metal/polymer constrained cemented or uncemented prosthesis (KWZ) Class II per 21 CFR 888.3360 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (KWL) Class II per 21 CFR 888.3390 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (KWY) Class II per 21 CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (LPH) Class II per 21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (OQI)

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

- Smith & Nephew REDAPT™ Revision Femoral System (K151902) – Primary Predicate
- Zimmer Biomet Arcos Interlocking Distal Stem (K100469) – Additional Predicate
- Signature Orthopaedics Spartan Hip Stem (K192883) – Additional Predicate
- Signature Orthopaedics Origin Hip Stem, Femoral Head, Logical PX-Series Acetabular Shell, Logical G-Series Acetabular Shell, Logical Acetabular (K121297) – Reference Device
- Signature Orthopaedics World Hip Stem World Cup, World Liner (K201278) – Reference Device

Device Description:

The Longboard Revision Stem is a femoral stem and a partially threaded distal locking screw intended for single use and cementless fixation for revision hip arthroplasties. The components are manufactured from titanium alloy as per ISO 5832-3 and ASTM F136 and the stem has a titanium alloy grit blast along the body. The Longboard Revision Stem is a symmetrical with a neck angle of 135°. The stem body is tapered and finned, while the distal tip is finless to allow for initial version adjustments. The stem neck features a 12/14 taper which allows for compatibility with Signature Orthopaedics' range of previously cleared femoral head components.

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 & fracture non-union or mal-union

• 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, hemiarthroplasty, surface replacement, or total hip replacement

• Dislocation risks (when used with SignaSure Dual Mobility System)

Signature Orthopaedics' Longboard Revision Stem is intended for individuals undergoing revision surgery of the hip only.

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Comparison of Technological Characteristics:

The subject and predicate device have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are similar between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structure support mechanism
- Principle of operation
- Sizes
- Design

Performance Testing:

Non-clinical testing and engineering evaluations were conducted to verify that the performance of the Signature Orthopaedics Longboard Revision Hip Stem is adequate for anticipated in-vivo use. The following non-clinical testing was carried out on the worst-case sizes of the subject devices:

- Range of Motion
- Stem and Neck Fatigue FEA
- Stem and Neck Fatigue Testing

Testing was done in accordance with the following testing standards:

- ISO 21535 Non-active surgical implants – Joint replacement implants – Specific requirements for hip joint replacement implants
- ASTM F2996 Standard Practice for Finite Element Analysis (FEA) of Non-Modular Metallic Orthopaedic Hip Femoral Stems
- ISO 7206-4 Partial and total hip joint prosthesis – Part 4: Determination of endurance properties and performance of stemmed femoral components
- ISO 7206-6 Partial and total hip joint prostheses – Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components
- ASTM F543 Standard Specification and Test Methods for Metallic Medical Bone Screws

The results of non-clinical testing show that the strength of the Signature Orthopaedics Longboard Revision Hip Stem is sufficient for their intended use and substantially equivalent to the legally marketed predicate device.

Substantial Equivalence:

The Longboard Revision Hip Stem have the same intended use and same indications for use as the predicate devices. The subject devices use the same operating principle, incorporate the same basic design, and are manufactured using the same materials as the predicate devices.

Any differences do not raise new questions of safety and effectiveness as established with performance testing. The subject devices are at least as safe and effective as the legally marketed predicate devices.