March 12, 2026

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

Re: K252824
Trade/Device Name: Evolve AP Cup, World Finned Cup, World G-Zero Liner and Oddball Femoral Head
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JDI, MEH, LPH, KWZ
Dated: February 13, 2026
Received: February 13, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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)*
K252824

Device Name
Evolve AP Cup, World Finned Cup, World G-Zero Liner and Oddball Femoral Head

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, Nebula, 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), Origin Cemented 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.

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:	Evolve AP Cup, World Finned Cup, World G-Zero Liner and Oddball Femoral Head
Common Name:	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:	12 MARCH 2026
Classification:	888.3350 - Hip joint metal/polymer semi-constrained cemented prosthesis 888.3353 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis 888.3310 - Hip joint metal/polymer constrained cemented or uncemented prosthesis
Product Code:	JDI, MEH, LPH, KWZ
Predicate Devices:	Substantial equivalence to the following devices is claimed: <u>Evolve AP Cup and Evolve AP Vit-E Cup</u> Primary Predicate • Howmedica Osteonics Corp., Stryker Trident All Poly Cup, K001956 Additional Predicates • Zimmer Biomet, ZCA All-Poly Acetabular Cup, K191449 • Signature Orthopaedics, Logical Vit-E Liner, K241690 <u>World Finned Cup</u> Primary Predicate

SignatureOrtho™

- Signature Orthopaedics, World Cup, K201278

Additional Predicate

- Signature Orthopaedics, Logical-C Cup, K153131

World G-Zero Liner and Oddball Femoral Head

Primary Predicate

- Biomet, G7 Freedom Liners and Freedom Head, K142882

Additional Predicate

- Signature Orthopaedics, Signature CoCr Femoral Head, K121297

Device Description:

The Evolve AP and Evolve AP Vit-E Cups are manufactured of UHMWPE and GUR1020-E respectively and are all-polyethylene acetabular cups intended for cemented use. The Evolve Cups are compatible with Signature Orthopaedics Signature Femoral Heads. The Evolve AP Vit-E Constrained Cup is contraindicated for use with Signature Orthopaedics Origin-NS and Cemented TSI Femoral Stem.

The World Finned Cup is manufactured from Ti6Al4V and is a cementless acetabular cup featuring external fins to provide extra fixation and reduced rotation of the cup. The World Finned Cup is compatible with Signature Orthopaedics World Liners.

The World G-Zero Liner is manufactured from UHMWPE GUR1020-E and is a constrained acetabular liner for use in conjunction with the Signature Orthopaedics World Cups in total hip arthroplasty. The Oddball Femoral Head is manufactured from CoCr and is compatible with the World G-Zero liners to complete the constrained hip replacement. Both the G-Zero Constrained Liner and the Oddball Femoral Head are contraindicated for use with Signature Orthopaedics Origin-NS and Cemented TSI Femoral Stem.

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, Nebula, 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), Origin Cemented 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

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:

Evolve AP Cup and Evolve AP Vit-E Cup

The Evolve Cups are the same as their predicates in fixation method, shape variants, size range, dimensions and material, and similar in poly thickness, internal and outer diameter and cement spacer thickness.

World Finned Cup

The World Finned Cups are the same as the predicates in material, fixation method, internal shell geometry, modularity, outer diameter, coating material and shell insertion feature, and similar in external shell geometry.

World G-Zero Liner

The World G-Zero Liner is the same as the predicate in modularity, material, and locking and retaining features, and similar in size, thickness and compatibility.

Oddball Femoral Head

The Oddball Femoral Head is the same as the predicate in material and taper connection and similar in size and external geometry.

Performance Testing:

The following non-clinical testing, engineering analysis and rationales were conducted to verify that the performance of the Signature Orthopaedics Evolve AP Cup, World Finned

Cup, World G-Zero Liner and Oddball Femoral Head is adequate for anticipated in-vivo use:

- Range of Motion (ISO21535)
- Lever-out of femoral head from constrained liner
- Disassembly of liner from shell engineering analysis
- Impingement performance engineering analysis
- Cup deformation engineering analysis
- Cup fatigue engineering analysis
- Wear performance rationale
- Coating Characterisation rationale

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 F1820 – Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices
- ISO 7206-12 – Implants for surgery – Partial and Total hip joint prosthesis – Part 12 – Deformation test method for acetabular shells
- ASTM F3090 – Standard Test method for Fatigue Testing of Acetabular Devices for Total Hip Replacement

The results of non-clinical testing show that the strength of the Signature Orthopaedics Evolve AP Cup, World Finned Cup, World G-Zero Liner and Oddball Femoral Head are sufficient for their intended use and substantially equivalent to the legally marketed predicate device.

Substantial Equivalence:

The Evolve AP Cup, World Finned Cup, World G-Zero Liner and Oddball Femoral Head have the same intended use and same indications for use as the predicate device. The differences in technological characteristics between the subject and predicate devices do not raise new questions of safety and effectiveness. The non-clinical testing, engineering analysis and rationales provided demonstrate that the subject devices are substantially equivalent to the predicate devices.