



September 24, 2021

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

Re: K211505

Trade/Device Name: Encore 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: MEH, LZO

Dated: August 18, 2021

Received: August 24, 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](mailto: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

## 1 INDICATIONS FOR USE STATEMENT

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510(k) Number (if Known): K211505

Device Name: Encore Hip 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, Aria, Remedy, TSI, Pegasus, Spartan, World and Encore 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 Insert is indicated for use with a 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

Prescription Use: Yes  
(Part 29 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use: No  
(Part 29 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

## 2 510(K) SUMMARY

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<b>Manufacturer:</b>	Signature Orthopaedics Pty Ltd 7 Sirius Road Lane Cove, NSW 2066 Australia
<b>Device Trade Name:</b>	Encore Hip Stem
<b>Common Name:</b>	Cementless Hip Replacement Prosthesis
<b>Contact:</b>	Dr. Declan Brazil Managing Director of Signature Orthopaedics
<b>Prepared By:</b>	Signature Orthopaedics Pty Ltd 7 Sirius Road Lane Cove, NSW 2066 Australia Phone: +61 (2) 9428 5181 Fax: +61 (2) 8456 6065
<b>Date Prepared:</b>	18 <sup>th</sup> of August, 2021
<b>Classification:</b>	Class II as per 21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (MEH) Class II as per 21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (LZO)
<b>Predicate Devices:</b>	Primary Predicate <ul style="list-style-type: none"><li>Signature Orthopaedics' Spartan Stem (K192883)</li></ul> Reference Predicate <ul style="list-style-type: none"><li>Signature Orthopaedics' Origin Stem (K121297)</li><li>Zimmer Biomet's Fitmore Stem (K071723)</li></ul>

**Device Description:**

Signature Orthopaedics' Encore Hip Stem is manufactured from forged titanium alloy (Ti6Al4V) as per ISO 5832-3 and ASTM F136. The Encore Stem is straight and tapered with a rectangular cross-section. The stem has a polished distal tip to reduce fixation leading to proximal stress shielding. It features a titanium and hydroxyapatite plasma spray proximal coating below its resection line.

**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

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- 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

### **Summary of Technological Characteristics:**

The Encore Hip Stem shares the following technological characteristics as its predicate devices:

- The Encore Stem is intended for cementless fixation which is the same intended use as its predicate device.
- The Encore Stem has the same indications for use as its predicate device.
- The Encore Stem is manufactured from the same materials as its predicate device.
- The Encore Stem has the same proximal coating as its predicate device.
- The Encore Stem has the same taper connection as its predicate device.
- The Encore Stem has the same surface finish as its predicate device
- The Encore Stem has the same femoral head options as its predicate device.

The following are the technological differences between the Encore Stem and its predicate device:

- The Encore Stem is sterilised via a different method compared to its predicate device

**Performance Testing:**

Non-clinical testing and engineering evaluations were conducted to verify that the performance of the Encore Hip Stem is adequate for anticipated in-vivo use. No animal or clinical testing was required to support substantial equivalence. Non-clinical testing carried out included:

- Range of Motion Testing
- Stem and Neck Fatigue FEA
- Stem and Neck Fatigue Testing
- Rim Impingement Analysis

**Substantial Equivalence Conclusion:**

Signature Orthopaedics' Encore Stem has the same intended use, indications for use, material and similar design features as Signature Orthopaedics' Spartan Stem (K192883) and non-clinical testing support the substantial equivalence claim.