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/combo-

ination-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,

Vesa Vuniqi, 
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
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 and Pegasus femoral stems, SignaSure Cementless Cup and Logical acetabular cups are intended for cementless fixation only. Signature Orthopaedics' Evolve and Cemented TSI femoral stems, and SignaSure Cemented Cup are intended for cemented fixation only. 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)

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)
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
Food and Drug Administration
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.*
510(K) SUMMARY

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

Device Trade Name: Signature Ceramic Femoral Head

Common Name: 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: 26 July 2019

Classification: Class II per 21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or non-porous uncemented prosthesis (LZO)

Predicate Devices:
Primary Predicate

• Signature Orthopaedics Signature Ceramic Femoral Head (K121297)

Additional Predicate

• ICONACY Orthopedic Implants ICONACY I-Hip Ceramic Head (K151307)

Device Description:
The modular Signature Ceramic Femoral Head is composed of alumina matrix composite with zirconia reinforcement, manufactured as per ISO 6474-2. It has a 12/14 taper which is identical to the taper on Signature Orthopaedics’ range of femoral heads. The device is compatible for use across any of Signature Orthopaedics’ total hip component range, and articulates with UHMWPE acetabular liner.

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 and Pegasus femoral stems, SignaSure Cementless Cup and Logical acetabular cups are intended for cementless fixation only. Signature Orthopaedics’ Evolve and Cemented TSI femoral stems, and SignaSure Cemented Cup are intended for cemented fixation only. 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

Non-Clinical Testing:
Non-clinical testing and engineering evaluations were conducted to verify that the performance of the Signature Ceramic Femoral Head is equal or better than the predicate device and therefore adequate for anticipated in-vivo use. The following non-clinical tests were carried out on the worst case sizes of Signature Ceramic Femoral Heads:

- Axial Compression Test
- Fatigue Test
- Post Fatigue Ultimate Compression Strength Test
- Static Pull-Off Test
- Static Torsion Test
Substantial Equivalence:
The Signature Ceramic Femoral Head has the same intended use, indications for use, design and materials as the rest of the relevant Signature Orthopaedics’ ceramic femoral head range (K121297) and ICONACY’s I-Hip Ceramic Femoral Head (K151307).

Comparison of technological characteristics
The subject device has the same material, manufacturing process, body contact, design and sterilization method as the predicate devices. The subject and Signature Ceramic Head (CeramTec) predicate device differ in the subcontract manufacturer.