Signature Orthopaedics Pty Ltd.
Declan Brazil
Mananging Director
7 Sirius Road
Lane Cove, 2066 Au

August 14, 2020

Re: K191708
Trade/Device Name: Origin Stem, Evolve Stem, Aria Hip Stem, Remedy Stem, CoCr Femoral Head
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, MEH, KWZ, OQG, LZO, KWY
Dated: July 9, 2020
Received: July 20, 2020

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vesa Vuniqi
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191708

Device Name
Origin Stem, Evolve Stem, Aria Hip Stem, Remedy Stem, CoCr 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 treaent, 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 and Logical acetabular cups are intended for cementless fixation only. Signature Orthopaedics' Evolve, Cemented TSI (both CoCr and HNSS variants) and Cemented Origin femoral stems 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)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

Manufacturer:	Signature Orthopaedics Pty Ltd 7 Sirius Road Lane Cove, NSW 2066 Australia
Device Trade Name:	Origin Stem Evolve Stem Aria Hip Stem Remedy Stem CoCr Femoral Head
Common Name:	Hip Replacement Prostheses
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:	August 14th, 2020
Classification:	LPH - Hip joint metal/polymer/metal semi-constrainted porous-coated uncemented prosthesis per 21 CFR 888.3358 MEH - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis per 21 CFR 888.3353 KWZ - Hip joint metal/polymer constrained cemented or uncemented prosthesis per 21 CFR 888.3310 OQG - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3358 LZO - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis per 21 CFR 888.3353 KWY – Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis per 21 CFR 888.3390
Predicate Devices:	Substantial equivalence to the following devices is claimed:

Primary Predicate:

- Signature Orthopaedics Origin Coxa Vara hip stem (K161155)

Secondary Predicate:

- 40 – 42mm BiPolar Head and 22mm Femoral Head (K163081)
- Signature Orthopaedics Origin hip stem (K121297)
- Signature Orthopaedics Aria hip stem (K121297)
- Signature Orthopaedics CoCr femoral head (K121297)
- Signature Orthopaedics Remedy hip stem (K133370)
- Signature Orthopaedics Evolve hip stem (K133370)
- FMP Constrained Liners (K023794)
- X-alt HXL Poly Liners (K072154)
- X-alt Highly Cross Linked Acetabular Liner with Vitamin E (K130365 & K140130)
- Foundation Porous Coated Hemispherical Acetabular Cup (K974093)
- FMP Hemispherical Shells (K974093)
- Foundation Porous Coated Flared Rim Acetabular Cup (K974095)
- Foundation Porous Acetabular System (K973119)
- EMPOWR Acetabular System, Cup (K190057)
- EMPOWR Acetabular System, Liner (K190057)
- Biolox Ceramic Femoral Head (K082844)
- Encore Medical BiPolar Head (K953510)

Device Description:

The purpose of this 510(k) application is to extend the compatibility of the subject devices between Signature Orthopaedics and Encore Medical components. The subject devices themselves have not undergone any changes.

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 treaent, 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
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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

Performance Testing:

The following non-clinical testings were evaluated as part of the engineering evaluations:

- Ceramic Head Testings per ISO 7206-10
- Ceramic Head Fatigue Burst Testing and Rotational Stability per Ceramtec Protocol
- Range of Motion per ISO 21535
- Rim Impingement per ASTM-F2582-14
- Stem Body Fatigue per ISO 7206-4
- Stem Neck Fatigue per ISO 7206-6
- Articulating Surface Wear per ISO 14242-1
- Head – Constrained Liner Assembly per Custom Protocol
- Head – Constrained Liner Disassembly per ISO 7206-10
- Head Pull Out per ISO 7206-10
- Fretting Corrosion Testing per ASTM-F1875
- Head Pull Out from BiPolar
- Femoral Head – Constrained Liner Lever-Out Disassembly

The engineering evaluations concluded that the performance of the subject devices will remain at least equivalent to the predicate devices when used in combinations as per the expanded compatibility.

Substantial Equivalence:
There are no changes to the indications for use or technology including features and material except for the principles of operation. This 510k is for a change in principle of operation where the compatibility of the subject devices are extended. The change in principle of operation of the subject devices was assessed and found to remain substantially equivalent to the predicate devices.

Comparison of technological characteristics

The subjected devices were not subjected to any technological changes, therefore, remain exactly the same as their predicate devices which were originally cleared.