DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 19, 2016

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

Re: K161155
Trade/Device Name: Origin Coxa Vara 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, KWZ
Dated: April 21, 2016
Received: April 25, 2016

Dear Dr. 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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1 INDICATIONS FOR USE STATEMENT

510(k) Number (if Known): K161155

Device Name: Origin Coxa Vara 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, NEO-T, Remedy and Pegasus femoral stems, and Logical acetabular cups are intended for cementless fixation only. Signature Orthopaedics' Evolve 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

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

2 510(K) SUMMARY

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

Device Trade Name: Origin Coxa Vara Hip Stem

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: April 21st, 2016

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

Class II per 21 CFR 888.3310: Prosthesis, Hip, Constrained, Cemented Or Uncemented, Metal/Polymer (KWZ)

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

- Signature Orthopaedics Origin Stem (K121297)
- Landos Corail (K953111)
- DePuy's Corail AMT Hip Prosthesis (K042992)

Device Description:

The Signature Orthopaedics Origin Coxa Vara Hip Stem is manufactured from titanium alloy per ASTM F136 and below the resection line is coated with HA per ISO 13779-2. The stem is straight and tapered with a lateral chamfer to aid insertion. The stem has both vertical and horizontal grooves to resist axial and torsional loading. The stem has a collar and a shallower neck angle suitable for coxa vara patients.

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, NEO-T, Remedy and Pegasus femoral stems, and Logical acetabular cups are intended for cementless fixation only. Signature Orthopaedics' Evolve 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

Performance Testing:

Non-clinical testing and engineering evaluations were conducted to verify that the performance of the Origin Coxa Vara Hip Stem is adequate for anticipated in-vivo use. Non-clinical testing carried out on the Origin Coxa Vara Hip Stem was femoral stem and neck fatigue testing. Engineering evaluation demonstrated that the Origin Coxa Vara Hip Stem presents a greater challenge to femoral stem and neck fatigue testing than the previously tested Origin Hip Stem range (per K121297). The following non-clinical testing was omitted from this 510(k) because engineering evaluation demonstrated that the Origin Coxa Vara Hip Stem falls within the scope of testing submitted with K121297 for the Origin Hip Stem:

- Range of motion analysis
- Modular component connection strength testing
- Various coating characterization, abrasion and adhesion strength testing

Substantial Equivalence:

The Origin Coxa Vara Hip Stem has the same intended use, indications for use, materials and design as the Origin Hip Stem (per K121297), excluding the neck geometry. The Origin Coxa Vara Hip Stem neck geometry is similar to the Coxa Vara Corail Hip Stem (per K953111 and K042992). Non-clinical testing results support the substantial equivalence claim. The Origin Coxa Varal Hip Stem is expected to perform adequately during clinical use.