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

January 29, 2018

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

Re: K163081
Trade/Device Name: 40-42mm BiPolar Head and 22mm Femoral Head
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metal/Polymer Cemented Or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: KWY
Dated: January 19, 2018
Received: January 22, 2018

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. 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,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K163081

Device Name

40-42mm BiPolar Head and 22mm Femoral Head

Indications for Use *(Describe)*

Signature Orthopaedics' Evolve UniPolar Head and BiPolar Head are intended for hemihip 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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Signature Orthopaedics Pty Ltd

2 510(K) SUMMARY

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

Device Trade Name: 40-42mm BiPolar Head and 22mm 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: January 19th, 2018

Classification: Class II per 21 CFR 888.3390: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (KWY)

Predicate Devices:

Primary Predicate:

- Signature Orthopaedics BiPolar Head (K133370)
- Signature Orthopaedics Femoral Head (K121297)

Secondary Predicate:

- DePuy Self-Centering Hip (K812672)
- Medacta Bipolar Heads (K091967)

Reference Predicate:

- Signature Orthopaedics UniPolar Head (K143184)

Device Description:

The BiPolar Head consists of a stainless steel outer shell (per ISO5832-9) and a UHMWPE insert (per ASTM F648). The outer shell is highly polished to articulate against the patient's natural acetabulum. The insert articulates against a Signature Orthopaedics 22 or 28mm cobalt-chrome femoral head (K121297). The femoral head connects to a femoral stem from Signature Orthopaedics' range to complete the hip hemi-arthroplasty.

Indications for Use:

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:

Bacterial endotoxin levels were evaluated on the final finished form of the subject device using the LAL method. Non-clinical testing and engineering evaluations were conducted to verify that the performance of the 40-42mm BiPolar Heads are adequate for anticipated in-vivo use. Non-clinical testing included:

- Range of motion analysis
- Component connection strength and fretting corrosion testing
- BiPolar head disclamping resistance testing

Substantial Equivalence:

The 40-42mm BiPolar Heads have the same intended use, indications for use, materials and design as the Signature Orthopaedics BiPolar Heads (per K133370). The 40-42mm BiPolar Heads differ from the Signature Orthopaedics BiPolar Heads (per K133370) only in the size range. The 40-42mm BiPolar Heads expand Signature Orthopaedics BiPolar Heads' size range to match the 40-42mm diameter DePuy Self Centering Hip (per K812672) and Medacta Bipolar Head (per K091967) sizes. The 22mm Femoral Head is identical to the Signature Orthopaedics Femoral Heads (per K121297) excluding the outer diameter, which has been reduced to 22mm for compatibility with the 40-42mm BiPolar Heads. Non-clinical testing results support the substantial equivalence claim.