Signature Orthopaedics Pty Ltd

JUL 2 2 2014

2 510(K) SUMMARY

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

Device Trade Name: Remedy™, Pegasus™ and Evolve™ Hip Stems and BiPolar Head

Common Name: Hip Prosthesis

Contact: Dr. Declan Brazil
Managing Director

Prepared By: Signature Orthopaedics Pty Ltd
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Date Prepared: October 30th, 2013

Classification: Class II per 21 CFR 888.3358: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (LPH)
Class II per 21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (LZO)
Class II per 21 CFR 888.3350: Hip joint metal/polymer semi-constrained cemented prosthesis (JDI)
Class II per 21 CFR 888.3390: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (KWY)

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

- Signature Orthopaedics Origin Total Hip System (K121297)
- DePuy Titanium Tri-Lock Hip Stem (K010367)
- Smith & Nephew SL PLUS Standard and Lateral Femoral Hip Stem (K072852)
- Howmedica Exeter Hip Stem (K110290)
- Zimmer MS-30 Femorall Stem (K040803)

Signature Orthopaedics Pty Ltd

- Howmedica Exeter Distal Centralizer (K974054)
- Smith & Nephew Buck Cement Restrictor (K791125)
- DePuy Self-Centering Hip (K812672)
- Medacta Bipolar Heads (K091967)

Device Description:

The Remedy™ and Pegasus™ hip stems are intended for cementless use in total hip arthroplasty. The Evolve™ hip stem is intended for cemented total hip arthoplasty. The Remedy™, Pegasus™ and Evolve™ hip stems connect to a femoral head (cobalt-chrome alloy or ceramic) via 12/14 taper connection.

The Remedy™ Hip Stem has a tapered wedge geometry. The stem is manufactured from titanium alloy per ASTM F136. The proximal stem is porous coated with titanium beads and particles per ASTM F67 and the distal stem is matte finished.

The Pegasus™ is a double tapered, straight stem with rectangular cross-section. The stem has a lateral wing for engaging the greater trochanter. The stem is manufactured from titanium alloy per ASTM F136. The stem is grit blasted below the resection line.

The Evolve™ Hip Stem is a highly polished, tapered wedge stem with a rounded cross-section. The Evolve™ Hip Stem is manufactured from high nitrogen stainless steel per ISO 5832-9. The Evolve™ Hip Stem is available in two variants, the Masters series and the Helios Series. Both variants share similar general geometry but are sized differently to provide a more complete range. The Evolve™ Hip Stem includes two accessories, the Evolve™ Distal Centralizer and Evolve™ Cement Plug. The Evolve™ Distal Centralizer is a PMMA cap that sits on the end of the Evolve™ Hip Stem and centralizes it within the femoral canal. The Evolve™ Cement Plug is manufactured from polyethylene per ASTM F648 and is pressed into the femoral canal prior to inserting the Evolve™ Hip Stem to allow cement pressurization.

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 28mm cobalt-chrome femoral head (K121297). The 28mm femoral head connects to a femoral stem from Signature Orthopaedics' range to complete the hip hemi-arthroplasty.

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' BiPolar Head is intended for hemi-hip arthroplasty only, where the natural acetabulum does not require replacement. The BiPolar Head is 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 Remedy™, Pegasus™ and Evolve™ Hip Stems and BiPolar Head are adequate for anticipated in-vivo use. Non-clinical testing included:

- Range of motion analysis
- Component connection strength and fretting corrosion testing
- Ceramic head burst testing
- Femoral stem fatigue testing
- Various coating characterization, abrasion and adhesion strength testing
- BiPolar head disclamping resistance testing

Substantial Equivalence:

The Remedy™ Hip Stem's design is similar to the DePuy Titanium Tri-Lock Hip Stem (K010367) predicate device and the porous coating is identical to the Signature Orthopaedics Logical G-Series Acetabular Cup (K121297). The Pegasus™ Hip Stem's design is similar to the Smith & Nephew SL PLUS Hip Stem (K072852) and the Zimmer Zweymuller SL Hip Stem (K962101) predicate devices. The Evolve™ Hip Stem's design is similar to the Howmedica Exeter Hip Stem (K110290). The Evolve™ Hip Stem's distal centralizer and cement plug are similar to those of the Exeter stem, K974054 and K980843 respectively. The BiPolar Head's design is similar to the DePuy Self-Centering Hip (K812672) predicate device. The Remedy™, Pegasus™ and Evolve™ Hip Stems are identical to the Signature Orthopaedics Total Hip System (K121297) in terms of intended use, indications for use, modular connection design, material, sterilization and packaging. The BiPolar head also shares identical modular connection design, material, sterilization and packaging as the Signature Orthopaedics Total Hip System (K121297), but it is intended for use as part of a hip hemi-arthroplasty. Non-clinical testing results support the substantial equivalence claim. The Remedy™, Pegasus™ and Evolve™ Hip Stems and BiPolar Head are expected to perform adequately during clinical use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 22, 2014

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

Re: K133370
Trade/Device Name: Remedy™, Pegasus™ and Evolve™ Hip Stems and BiPolar 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, LZO, JDI, KWY
Dated: June 19, 2014
Received: June 26, 2014

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" (21CFR 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,

Lori A. Wiggins

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

Enclosure

Signature Orthopaedics Pty Ltd

1 INDICATIONS FOR USE STATEMENT

510(k) Number (if Known): - K133370

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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)

Elizabeth L. Frank -S

Division of Orthopedic Devices