K121297

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1 510(K) SUMMARY

DEC 2 8 2012

Manufacturer:
Signature Orthopaedics Pty Ltd
126 Greville Street
Chatswood, NSW 2067
Australia

Device Trade Name: Origin™ Total Hip System

Common Name: Total Hip Prosthesis

Contact:
Dr. Declan Brazil
Managing Director of Signature Orthopaedics

Prepared By:
Signature Orthopaedics Pty Ltd
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Australia
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Date Prepared: April 20th, 2012

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 888.3358: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (LPH)

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

- Landos Corail (K953111)
- DePuy's Corail AMT Hip Prosthesis (K042992)
- Exactech's Novation Element Hip Prosthesis (K080980)
- DePuy Pinnacle Acetabular System (K000306, K001534)
- DePuy Pinnacle with Gription Acetabular Cups (K093646, K071784)
- Biomet Taperloc 12/14 Taper Femoral Component (K043537)
- Howmedics Osteonics Corp. TMZF Press Fit HA Stem and TMZF Press Fit Plus HA Stem (K994366)
- APEX Modular Hip System BIOLOX delta Femoral Head (K101451)

Device Description:

The system is modular and consists of the Signature Orthopaedics Origin™ and NEO-T Hip Stem, Femoral Heads, and PX-Series and G-Series Acetabular Cups.

The Signature Orthopaedics Origin™ 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 Signature Orthopaedics NEO-T™ Hip Stem is a porous coated femoral stem manufactured from titanium alloy per ASTM F136. The proximal stem below the resection line is porous coated with titanium powder per ASTM F1580. The stem is straight and tapered with a rectangular cross-section. The stem has a distal slot and lateral chamfer to ease insertion.

Both stems are available in standard and high offset neck geometries. Each stem's neck has a 12/14 morse taper for connection of a Cobalt Chrome or Ceramic (BIOLOX forte or BIOLOX Delta) femoral head.

The Logical™ PX-Series and G-Series Acetabular Cups are metal backed cementless acetabular cups with highly cross-linked polyethylene liners. Both series of acetabular cup consist of a porous coated shell manufactured from titanium alloy per ASTM F136, and a modular liner manufactured from cross-linked UHMWPE per ASTM F648. The PX-Series and G-Series shells differ in their shell's porous coating. The PX-Series is coated with titanium beads while the G-series is coated with a combination of titanium beads and particles. Both series of cups are available with either no holes or three holes to allow the use of bone screws to supplement fixation.

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

Components of the Signature Orthopaedics hip replacement range are intended for cementless fixation only.

Performance Testing:

Non-clinical testing and engineering evaluations were conducted to verify that the performance of the Origin™ Total Hip System is adequate for anticipated in-vivo use. Non-clinical testing included:

- Range of motion analysis
- Articular surface wear simulation
- Modular component connection strength testing
- Ceramic head burst testing
- Femoral stem fatigue testing
- Liner impingement testing
- Cup Liner Push, Lever Out and Torque Testing
- Bone screw torsion testing
- Various coating characterization, abrasion and adhesion strength testing
- Various crosslinked UHMWPE characterization, chemical and mechanical testing

Substantial Equivalence:

The Origin™ Total Hip System has similar intended use, indications for use, materials and design to the predicate devices. Non-clinical testing results support the substantial equivalence claim. The Origin™ Total Hip System is 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

Signature Orthopaedics, Pty Ltd
% Dr. Declan Brazil
Managing Director of Signature Orthopaedics
126 Greville Street
Chatswood NSW 2067
Australia

Letter dated: December 28, 2012

Re: K121297
Trade/Device Name: Origin™ Total Hip System
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, LPH
Dated: December 21, 2012
Received: December 26, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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

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): K121297

Device Name: Origin™ Total Hip System

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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)

Krishna Asundi, PhD
Division of Orthopedic Devices