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

June 3, 2016

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

Re: K153131
Trade/Device Name: Logical C-series Acetabular Shell, Logical Constrained Liner, Logical Constrained Liner Collar, Logical 20º Hooded Acetabular Liner
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, KWZ
Dated: April 20, 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 Parts 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,

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): - K153131

Device Name: Logical C-Series Shell, Constrained Liner and 20° Hooded Liner

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)

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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:** Logical C-Series Shell, Constrained Liner and 20° Hooded Liner

**Common Name:** Total 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:** October 26th, 2015

**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)

Class II per 21 CFR 888.3310: Hip joint metal/polymer constrained cemented or uncemented prosthesis (KWZ)

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

- DePuy Pinnacle Duofix HA Acetabular Cup Prosthesis (K031495)
- Howmedica Osteonics Trident Acetabular Shells: PS-HA (K001448)
- DePuy Pinnacle Constrained Acetabular Liner (K043058, K052079, K071117)
- Pinnacle Acetabular System (K001534, K000306)
- Signature Origin Total Hip System (K121297)
- DePuy Duraloc Constrained Liner (K951301, K972596)
- Smith & Nephew Reflection Constrained Liner (K021803, K033442)

**Device Description:**

The Logical C-Series Acetabular Shell is a metal backed cementless acetabular cup that is compatible with a highly cross-linked polyethylene liner from the Origin Total Hip System predicate device (K121297), as well as the Logical Constrained Liner and Logical 20° Hooded Liner. The shell's substrate is manufactured from Ti6Al4V alloy per ASTM F136. The outer surface of the shell is sequentially coated with commercially pure titanium (per ASTM F1580) and Hydroxylapatite (per ISO 13779-2). The shell is available in no-hole, 3-hole or multi-hole configurations to allow use of bone screws for supplemental fixation.

The Logical Constrained Liner and the Logical 20° Hooded Liner are line range extensions to the Logical Liner per K121297. The Logical Constrained Liner differs from the original range in that it provides greater than 180 degree head coverage to constrain the head within liner. The Logical 20° Hooded Liner differs from the original range in that it incorporates a 20° hood as opposed to the original 10° hood. The Logical Constrained Liner and Logical 20° Hooded Liner are manufactured from highly cross-linked polyethylene (XLPE) identical to the Logical Liner per K121297. The Logical Constrained Liner further incorporates a titanium alloy collar to support the liner's rim. Furthermore, the Logical Constrained Liner is assembled with the Logical Shell and Logical Constrained Liner Collar via titanium alloy snapring. The Logical Constrained and 20° Hooded Liners articulate with a femoral head of appropriate diameter.

**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 Logical C-Series Shell, Constrained Liner and 20° Hooded Liner devices are adequate for anticipated in-vivo use. Non-clinical testing included:

- Range of motion analysis
- Shell stiffness testing
- Modular component connection strength testing
- Cup-Liner Push Out testing
- Head-Liner Assembly / Disassembly Testing
- Liner-Shell Assembly Testing
- Various coating characterization, abrasion and adhesion strength testing

**Substantial Equivalence:**

The Logical C-Series Shell, Constrained Liner and 20° Hooded Liner devices have similar intended use, indications for use, materials and design to the predicate devices. Non-clinical testing results support the substantial equivalence claim. The Logical C-Series Shell, Constrained Liner and 20° Hooded Liner devices are expected to perform adequately during clinical use.