



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

February 11, 2019

Re: K181340

Trade/Device Name: Cemented TSI Hip Stem
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JDI
Dated: May 18, 2018
Received: May 21, 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel S. Ramsey -S
2019.02.11 15:14:33
-05'00'

FOR 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): K181340

Device Name: Cemented TSI 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, Aria, Remedy, TSI and Pegasus femoral stems, and Logical acetabular cups are intended for cementless fixation only. Signature Orthopaedics' Evolve and Cemented TSI 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:	Cemented TSI Hip Stem
Common Name:	Cemented Hip Replacement 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:	May 18 th , 2018
Classification:	Class II per 21 CFR 888.3350: Hip joint metal/polymer semi-constrained cemented prosthesis (JDI)
Predicate Devices:	Primary Predicate - Signature Orthopaedics TSI Stem (K102172, re-branded from Global MSA) Additional Predicate - Signature Orthopaedics Evolve Stem (K133370) - Smith & Nephew Synergy Cemented Stem (K990369) Reference Predicate - Signature Orthopaedics Logical Cup (K121297)

Device Description:

The Signature Orthopaedics' Cemented TSI Hip Stems are manufactured from Forged CoCr per ASTM-F799. The Cemented TSI stem is a highly polished anatomically curved stem with a round cross-section intended for cemented use in total hip 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

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- 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 Cemented TSI Hip Stems are adequate for anticipated in-vivo use. The following non-clinical testings were carried out on the worst case sizes of the stems:

- Range of motion testing
- Stem fatigue testing
- CoCr Head Disassembly Test
- Ceramic Head Static Burst Test
- Ceramic Head Pull-Off Test

The subject device has been validated as non-pyrogenic.

Substantial Equivalence:

That Signature Orthopaedics' Cemented TSI stems have the same intended use, indication for use, materials and similar design features as the Signature Orthopaedics Evolve Stem (K133370), Smith & Nephew Synergy Cemented Stem (K990369) and the Signature Orthopaedics TSI Stem (K102172). Non-clinical testing results support the substantial equivalence claim.

Comparison of technological characteristics

Reconstructive total hip joint replacement is the technological principle for both the subject devices and the predicate devices. The subject and predicate devices are based on

the following same technological elements:

- The indication for use of the subject devices is the same as one or more of the predicate devices
- The intended surgery sites of the subject devices matches the intended surgery sites of at least one of the predicates
- The subject devices are manufactured from the same material as at least one of the predicates
- The subject devices are for use with cemented fixation, in line with at least one of the predicates
- The size range of the subject devices fall within the size range of the predicates
- The taper connection is identical to at least one of the predicates
- The device design (profile) is similar to at least one of the predicates
- The surface finish is identical to at least one of the predicates

The following technological differences exist between the subject and predicate devices:

- Some of the design features are different between the subject and predicate devices
- The metallic material used on at least one of the predicates differs to what is used in the subject devices
- The taper connection differs to at least one predicate device
- The surface finish differs to at least one predicate device