April 16, 2021

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

Re: K201047
Trade/Device Name: Fusion Taper 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: LZO, MEH, MBL
Dated: March 15, 2021
Received: March 19, 2021

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vesa Vuniqi
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if Known): K201047

Device Name: Fusion Taper System

Indications For Use:
Signature Orthopaedics' Fusion Taper System is 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, hemi-arthroplasty, surface replacement, or total replacement

Signature Orthopaedics' Fusion Taper System is intended for cementless fixation only.

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 Signature Orthopaedics Europe Ltd Unit A, IDA Business & Technology Park Garrycastle Athlone Westmeath N37 DY26 IRELAND
Device Trade Name:	Fusion Taper System
Common Name:	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:	15th of March, 2021
Classification:	Class II per 21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or non-porous uncemented prosthesis (MEH) Class II per 21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or non-porous uncemented prosthesis (LZO) Class II per 21 CFR 888.3358: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (MBL)
Predicate Devices:	Primary Predicates • Zimmer's Biolox Option Femoral Head and Taper Sleeve (K073567) Secondary Predicates • Signature Orthopaedics' Evolve UniPolar Head and Taper Sleeve (K143184) • Signature Orthopaedics' Signature Ceramic Femoral Head (K190704)

Reference Devices

- Signature Origin Stem (K121297)
- Signature Evolve Stem (K133370)
- Signature Orthopaedics NOOSA, NAMBUCCA and CAIRNS Lumbar Plate System (K163625)
- Signature World Hip System (K201278)

Device Description:

The Fusion Taper System consists of modular femoral heads and taper sleeves. The Fusion Taper Sleeve is manufactured from Ti6Al4V as per ISO 5832-3. The Fusion Ceramic Head is manufactured from an alumina matrix as per ISO 6474-2. All Fusion Heads are intended for total hip arthroplasty. The Fusion Heads connect to the femoral stem via a Fusion Taper Sleeve which has a 12/14 inner taper and 16/18 outer taper. Signature Orthopaedics Fusion Taper System is indicated for use with Signature Ti6Al4V femoral stems: TSI Stem (K102172), Origin Stem (K121297, K161155), Aria Stem (K121297), Remedy Stem (K133370), Spartan Stem (K192883), World Stem (K201278), and acetabular components: Logical Cup (K121297, K153131), Logical Liners (K121297), Logical 20deg Hooded Liners including lateralised variants (K153131), World Cup (K201278), and World Liner (K201278).

Indications for Use:

Signature Orthopaedics' Fusion Taper System is 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, hemi-arthroplasty, surface replacement, or total replacement
Signature Orthopaedics' Fusion Taper System is intended for cementless fixation only.

Summary of Technological Characteristics:

The Fusion Taper Sleeve has the same indications for use, body contact, sterilization method as Signature Orthopaedics' Signature Evolve UniPolar Taper Sleeve (K143184). The Fusion Taper Sleeve has the same intended use, indications for use, and taper sleeve material and connection as Zimmer's Biolox Option Taper Sleeve (K093363).
The Fusion Ceramic Head has the same indications for use, body contact, sterilization method is manufactured from the same material, has the same articular surface as Signature Orthopaedics' Signature Ceramic Head (K190704). The Fusion Ceramic Head has the same intended use and taper sleeve material and connection as Zimmer's Biolox Option Femoral Head (K073567).

Non-Clinical Performance Testing:

Non-clinical testing and engineering evaluations were conducted to verify that the performance of the Fusion Taper System is adequate for anticipated in-vivo use. Non-clinical testing carried out included:

- Range of motion analysis
- Component connection strength
- Fretting corrosion testing
- Burst strength, fatigue and post-fatigue testing on the Fusion Ceramic Head
- Rim impingement evaluation

The subject device has been validated as non-pyrogenic.

Substantial Equivalence Conclusion:
The subject devices are substantially equivalent to the predicate devices since it has the same intended use, indications for use, body contact, materials, design features, and sterilization. Non-clinical testing results support the substantial equivalence claim.