October 4, 2022

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

Re: K222380
Trade/Device Name: TriVerse Total Knee Replacement System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH, OIY
Dated: July 28, 2022
Received: August 5, 2022

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 and Part 809); 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,

Ting Song, PhD
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222380

Device Name

TriVerse Total Knee Replacement System

Indications for Use *(Describe)*

The patient should be skeletally mature to receive a knee replacement. Patients should have adequate bone stock and size to support and accept the prosthesis.

The patient's need for knee replacement should be due to one or more of the following conditions:

- Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis.
- Inflammatory degenerative joint disease including rheumatoid arthritis.
- Functional deformity such as varus, valgus or flexion deformities.
- Revision procedures where other treatments or devices have failed.

Signature Orthopaedics' TriVerse Total Knee Replacement System components are indicated for cemented application only.

Type of Use *(Select one or both, as applicable)*

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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:	TriVerse Total Knee Replacement System
Common Name:	TriVerse Knee
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:	28th July 2022
Classification:	Knee joint patellofemorotibial metal/polymer/metal semi-constrained cemented prosthesis. (JWH, 21 CFR 888.3560) Knee joint patellofemorotibial polymer+ Additive/metal/polymer + additive semi-constrained cemented prosthesis. (OIY, 21 CFR 888.3560)
Predicate Devices:	Primary Predicate • Biomet Vanguard Total Knee System (K113550) Reference Devices • Signature Orthopaedics World Knee System (K181530) • Signature Orthopaedics World Knee Total Knee System (K220737) • Signature Orthopaedics Active-X Knee System (K160159)

Device Description:

The TriVerse Total Knee System is a modular total knee replacement (TKR) system consisting of a femoral component, meniscal inserts, a locking bar for the meniscal insert, a patella and a tibial baseplate with a tibial post and bolt. The femoral component

and meniscal insert locking bar is manufactured from cobalt chrome. The femoral component are available as posterior stabilise and cruciate retaining variants, while meniscal inserts are available as posterior stabilised, posterior stabilised plus, cruciate retaining and anterior stabilised variants. All variants of the meniscal inserts as well as the patella components are manufactured from Vitamin-E Stabilized UHMWPE (HXLPE). The tibial post component is available as an I-Beam or Finned keel variant. The tibial base plate, bolt and post components are manufactured from titanium alloy.

Indications for Use:

The patient should be skeletally mature to receive a knee replacement. Patients should have adequate bone stock and size to support and accept the prosthesis.

The patient's need for knee replacement should be due to one or more of the following conditions:

- Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis.
- Inflammatory degenerative joint disease including rheumatoid arthritis.
- Functional deformity such as varus, valgus or flexion deformities.
- Revision procedures where other treatments or devices have failed.

Signature Orthopaedics' TriVerse Total Knee replacement components are indicated for cemented application only.

Summary of Technological Characteristics:

Reconstructive total knee joint replacement is the technological principle for both the subject device and the predicate devices. The subject and primary predicate devices are based on the same technological elements as listed below.

- The indication for use of the subject device is the same as the Biomet Vanguard Total Knee System.
- The intended surgery sites of the subject devices matches the intended surgery sites of the Biomet Vanguard Total Knee System
- The subject devices are manufactured from the same materials as the predicate Biomet Vanguard Total Knee System for femoral, meniscal and all components related to the tibial tray (tibial post, locking bolt) and insert locking bar.
- The modular locking mechanism of the tibial tray with a locking bar is the same as the Biomet Vanguard Total Knee system.
- The articulating surfaces and kinematics of the subject devices are the same as that of the Biomet Vanguard Total Knee System.
- The design features and size ranges of the subject device are the same as that of the Biomet Vanguard Total Knee System.

Performance Testing:

Non-clinical testing and engineering evaluations were conducted to verify that the performance of the TriVerse Total Knee System is adequate for anticipated in-vivo use. The following non-clinical testing was carried out:

- Range of Motion (ROM) testing
- Tibial Tray Fatigue testing
- Tibiofemoral constraint testing
- Meniscal bearing interlock strength testing

- Meniscal assembly usability testing
- Shear Fatigue of Tibial Post testing
- Patellofemoral contact area and stress testing

Substantial Equivalence Conclusion:

The TriVerse Total Knee System has the same intended use, indications for use, materials and similar design as the Biomet Vanguard Total Knee System (K113550). Non-clinical testing results support the substantial equivalence claim. The subject devices are expected to perform adequately during clinical use.