June 16, 2022

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

Re: K212870
Trade/Device Name: TLC Unicompartmental Knee System
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee Joint Femorotibial Metal/Polymer Non-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSX
Dated: April 27, 2022
Received: May 16, 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); 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, Ph.D.
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)*
K212870

Device Name
TLC Unicompartmental Knee System

Indications for Use *(Describe)*
The Signature Orthopaedics' TLC Unicompartmental Knee comprising the femur component, tibial component and meniscal inserts is designed for a single compartment replacement of the natural knee joint. The TLC Unicompartmental Knee is indicated for cemented use in partial knee arthroplasty procedures. Partial replacement of the articulating surfaces of the knee is indicated only when only one compartment of the joint is affected due to the compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

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.**

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## 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:** TLC Unicompartmental Knee System

**Common Name:** Unicompartmental Knee 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:** November 3rd,2021

**Classification:** Knee joint femorotibial metal/polymer non-constrained cemented prosthesis. (HSX, 21CFR 888.3520)

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

- Biomet Personal Partial Knee System (K161592) (Primary)
- Signature Orthopaedics World Total Knee Replacement System (K181530) (Reference)

**Device Description:**

The TLC Unicompartmental Knee system is a modular knee system consisting of a femoral component, meniscal insert and a tibial baseplate. The femoral component is manufactured from cast cobalt chromium alloy and are intended for use with bone cement. The tibial baseplate component is manufactured from titanium alloy and intended for use with bone cement. The meniscal insert is manufactured from UHMWPE.

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**Indications for Use:**

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**Summary of technological characteristics**

Reconstructive partial knee joint replacement is the technological principle for the subject device At a high level, the subject and predicate devices are based on the following same technological elements:

- The indication for use of the subject device is the same as the Biomet Persona Partial Knee System.
- The intended surgery sites of the subject devices matches the intended surgery sites of the Biomet Persona Partial Knee System
- The subject devices are manufactured from the same materials as the predicate Biomet Persona Partial Knee System, and the World Knee Total Knee System, for femoral, meniscal, and tibial tray components
- The subject devices are for use with cemented fixation which is in line with the Biomet Persona Partial Knee System
- The range of sizes of the subject devices are within the range of sizes of the Biomet Persona Partial Knee System for femoral, meniscal, and tibial tray components

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

- The technological principle is different between the subject device and one of the predicate devices i.e. World Total Knee Replacement System.
- Some of the design features are different between the subject and predicate devices like the highly congruent insert of the World Total Knee System.
- Some of the femoral size variants of the subject device are not available as compared to the Biomet Persona Partial Knee System.
- The modular locking mechanism of the tibial tray differs as compared to the Biomet Persona Partial Knee system and the World Total Knee System.

**Performance Testing:**

Non-clinical testing and engineering evaluations were conducted to verify that the performance of the TLC UniKnee system is adequate for anticipated in-vivo use. Non-clinical testing carried out on the TLC UniKnee system included:

- Range of motion analysis
- Modular component interlock strength testing

- Component contact area and stress testing
- Tibial plate fatigue testing
- Modular Component Assembly Testing

**Substantial Equivalence Conclusion:**

The TLC Unicompartmental Knee System has the same intended use, indications for use, materials and similar design as the Biomet Persona Partial Knee System (K161592) and the World Total Knee System (K181530). Non-clinical testing results support the substantial equivalence claim. The subject devices are expected to perform adequately during clinical use.