December 16, 2025

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

Re: K251771
Trade/Device Name: Cambridge Partial Knee
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: June 10, 2025
Received: June 10, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lixin Liu -S

Lixin Liu, 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)*
K251771

Device Name
Cambridge Partial Knee

Indications for Use *(Describe)*
The Signature Orthopaedics' Cambridge Partial Knee is designed for a single compartment replacement of the natural knee joint. The Cambridge Partial 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Manufacturer:	Signature Orthopaedics Pty Ltd 7 Sirius Road Lane Cove, NSW 2066 Australia
Device Trade Name:	Cambridge Partial Knee
Common Name:	Cambridge Partial 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:	11 DECEMBER 2025
Classification:	888.3520 – Knee joint femorotibial metal/polymer non-constrained cemented prosthesis HSX
Predicate Devices:	Substantial equivalence to the following devices is claimed: Predicate Device • Signature Orthopaedics, TLC Unicompartmental Knee System, K212870 Reference Devices • Biomet Inc., Vanguard M Series Unicondylar Tibial Bearings, K042093 • Biomet Inc., Oxford Unicompartmental Knee Femoral Component, K011138 • ASDM Pty Ltd, Active Unicompartmental Knee System, K060412

Device Description:

The Cambridge Partial Knee is a unicompartmental knee system consisting of a femoral component and tibial component (meniscal insert overmoulded onto the tibial baseplate).

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The femoral and tibial components are intended for use with bone cement. The implant is for fixed partial knee replacement. Each size tibial implant has two variants, right lateral/left medial (RLLM) and right medial/left lateral (RMLL) condyle.

The femoral component is a spherical, symmetrically designed prosthesis manufactured from cast cobalt chrome (CoCrMo). The meniscal bearing and tibial baseplate are a monobloc fixed tibial bearing consisting of a titanium (Ti6Al4V) baseplate overmoulded with UHMWPE GUR1020-E. The meniscal bearing is moulded over the tibial baseplate and machined to the correct size and geometry.

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Comparison of Technological Characteristics:

The subject and predicate device have similar technological characteristics, and the minor differences do not raise different questions of safety and effectiveness. Specifically, the following characteristics are similar between the subject and predicate:

- The Indications for Use for the subject and the predicate device are identical
- The tibial baseplate and femoral component materials of the subject and predicate device are identical
- Both the subject and predicate devices are intended for cemented fixation
- The anteroposterior and mediolateral lengths of the tibial components are similar between the subject and predicate devices
- Meniscal bearing thickness is similar between the subject and the predicate device
- Both the subject and predicate devices cover similar mediolateral size range in both femoral and tibial components
- Both predicate and subject knee systems are modular

The following are the technological differences between the subject device and the predicate:

- The subject device has a different bearing locking mechanism than the predicate
- The subject device tibial insert utilised Vitamin E UHMWPE while the predicate device utilised UHMWPE
- The anterior-posterior lengths of the femoral components differ slightly between the subject and predicate devices
- The subject device femoral component is symmetrical while the predicate device femoral component is asymmetrical

Performance Testing:

Non-clinical testing and engineering evaluations were conducted to verify that the performance of the Signature Orthopaedics Cambridge Partial Knee is adequate for anticipated in-vivo use. The following non-clinical testing was carried out on the worst-case sizes of the subject devices:

- Range of Motion
- Tibial Tray Fatigue Testing
- Tibial Component Overmould Strength
- Contact Area, Contact Stress and Wear Analysis

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- Femoral Fatigue Testing

Testing was done in accordance with the following testing standards:

- ASTM F1340-17 – Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Unicondylar Knee Joint Replacements
- ASTM F1800-19e1 – Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Plate Components of Total Knee Joint Replacements
- ASTM F3210-22 – Standard Test Method for Fatigue testing of Total Knee Femoral Components Under Closing Conditions
- ISO 14879-1:2020 – Implants for Surgery – Total Knee Joint Prosthesis Part 1: Determination of endurance properties of knee tibial plates
- ISO 21536:2023 – Non-active surgical implants – Joint replacement implants – Specific requirements for knee-joint replacements

The results of non-clinical testing show that the strength of the Signature Orthopaedics Cambridge Partial Knee is sufficient for their intended use and substantially equivalent to the legally marketed predicate device.

Substantial Equivalence:

The Cambridge Partial Knee has the same intended use and same indications for use as the predicate device. The subject device uses the same operating principle, incorporate the same basic design, and is manufactured using the same materials as the predicate device.

Any differences do not raise different questions of safety and effectiveness as established with performance testing. The subject devices are at least as safe and effective as the legally marketed predicate device.