



December 23, 2025

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

Re: K253239

Trade/Device Name: Active-V Total Knee System; World Total Knee System

Regulation Number: 21 CFR 888.3565

Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented
Prosthesis

Regulatory Class: Class II

Product Code: MBH, JWH

Dated: September 29, 2025

Received: September 29, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K253239

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Please provide the device trade name(s).

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Active-V Total Knee System;
World Total Knee System

Please provide your Indications for Use below.

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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 needs 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 device have failed
- Fractures that are unmanageable using other techniques

Signature Orthopaedics' World Knee/Active-V Knee replacement components may be intended for cemented or cementless use.

Please select the types of uses (select one or both, as applicable).

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

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510(k) SUMMARY

Manufacturer:	Signature Orthopaedics Pty Ltd 7 Sirius Road Lane Cove, NSW 2066 Australia
Device Trade Name:	1. Active-V Total Knee System 2. World Total Knee System
Common Name:	1. Total Knee Replacement System 2. Total Knee Replacement System
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:	22 nd December 2025
Classification:	888.3565 - Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis MBH 888.3560 - Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis JWH
Predicate Devices:	Substantial equivalence to the following devices is claimed: <u>Active-V Total Knee System</u> Primary Predicate <ul style="list-style-type: none">Signature Orthopaedics, World Total Knee System (K181530) Additional Predicates <ul style="list-style-type: none">Signature Orthopaedics, World Total Knee System (K223062)Signature Orthopaedics, Triverse Total Knee System (K222380)



Reference Device

- Signature Orthopaedics, Rx Knee System (K243680)

World Total Knee System - Line Extension

Primary Predicate

- Signature Orthopaedics, World Total Knee System (K181530)

Additional Predicates

- Signature Orthopaedics, World Total Knee System (K220737, K223062)

Reference Device

- Signature Orthopaedics, Rx Knee System (K243680)

Device Description:

Active-V Total Knee System

The Active-V Total Knee is a modular total knee system consisting of a femoral component, a meniscal insert, a patella, tibial baseplate with a fin keel and an external tibial augment. The femoral and tibial components are intended for cemented and cementless use. The tibial insert bearing components are available in cruciate retaining (CR) and ultracongruent (UC) variants while the femoral components are available in posterior stabilizing (PS) and CR variants. All components are intended for single use only.

The femoral component is an anatomically accurate designed prosthesis manufactured from cast cobalt chrome (CoCrMo) alloy. The tibial component is a modular symmetrical tray design, manufactured from Ti6Al4V Alloy. Cementless femoral components with plasma sprayed commercially pure titanium and hydroxyapatite coating with the option of titanium nitride coating are included. Tibial components with the same coating specifications as the femoral components are available. The tibial external augment is manufactured from the same Ti6Al4V alloy. The meniscal insert is available in CR and Medialconstrained (MC) variant surfaces, and is manufactured from Vitamin-E stabilized UHMWPE (HXLPE). The patella is a spherical, 3-peg patella design manufactured from Vitamin-E stabilized UHMWPE. Components are available for cemented or cementless use.

World Total Knee System - Line Extension

The World Knee line extension presented in this 510(k) is addition of the following components:

- Cementless femoral components with new coating specifications (plasma sprayed commercially pure titanium and hydroxyapatite coating with the option of titanium nitride coating)
- Tibial components with the modified coating specifications (same as the femoral components) and tibial tray to fin keel modular design
- Constrained condylar knee (CCK) variant of the all poly tibia component and meniscal insert, and medialconstrained (MC) variant of the meniscal insert
- Tibial external augment



The femoral component is an anatomically accurate designed prosthesis manufactured from cast cobalt chrome (CoCrMo) alloy. The tibial component is a modular symmetrical tray design, manufactured from Ti6Al4V Alloy. The tibial external augment is manufactured from the same Ti6Al4V alloy. The meniscal inserts and all poly tibia are manufactured from conventional Ultrahigh Molecular Weight Polyethylene (UHMWPE) and Vitamin E Stabilized and 100 kGy Crosslinked UHMWPE (Vit-E HXLPE). Components are available for cemented or cementless use.

Indications for Use:

Both subject devices have the same 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 needs 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 device have failed
- Fractures that are unmanageable using other techniques

Signature Orthopaedics' Active-V/World Total Knee components may be intended for cemented and cementless use.

Comparison of Technological Characteristics:

The subject and predicate devices have nearly identical technological characteristics, and the minor differences do not raise any different issues of safety and effectiveness. Specifically, the following characteristics are similar between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Fixation method
- Principle of operation
- Sizes
- Design

Differences with predicate devices exist with respect to available porous coatings, available constraint options, and tibial augment components.

Performance Testing:

Both subject devices' pre-clinical testing was planned following the guidance provided by the following FDA Guidance "Knee Joint Patellofemoral and Femorotibial Metal/Polymer Porous-coated Uncemented Prostheses". For non-applicable/not required testing, appropriate justification could be provided. Two sets of additional engineering evaluation were conducted to verify that the performances of the subject devices are adequate for anticipated in-vivo use. The following engineering evaluations were carried out on the worst-case sizes of the subject devices:

- Finite Element Analysis (FEA) performed on Active-V Knee Tibial Baseplate



- Range of Motion (ROM) Analysis performed on CCK all poly tibia/meniscal insert and MC meniscal insert

The combination of engineering evaluation results and scientific justification provided demonstrate that the Signature Orthopaedics' Active-V and World Total Knee Systems are sufficient for their intended use and substantially equivalent to the legally marketed predicate device.

Substantial Equivalence:

Both subject devices have the same intended use and same indications for use as the corresponding predicate devices. The subject devices use the same operating principle, incorporate the same basic design, and is manufactured using the same materials as the predicate devices.

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.

Conclusion:

Based on similarities in device design, materials, sizes, intended use, indications for use, packaging, sterilization, labeling, and performance testing to the predicate devices, the Active-V Total Knee System and World Total Knee System should perform in a substantially equivalent manner when used as indicated.