May 13, 2025

Signature Orthopaedics Pty Ltd
Dr. Declan Brazil
Chief Executive Officer
7 Sirius Road
Lane Cove West, NSW 2066
Australia

Re: K242674
Trade/Device Name: Freedom Posterior Cervical Screws
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG
Dated: May 1, 2025
Received: May 1, 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,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242674

Device Name

Freedom Posterior Cervical Screws

Indications for Use *(Describe)*

The Signature Orthopaedics Freedom Cervical Screw and Rod System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients (C1 to C7) as an adjunct to fusion in the treatment of the following acute and chronic instabilities and deformities of the cervical spine:

- traumatic spinal fractures and/or traumatic dislocations
- instability or deformity; failed previous fusions (e.g. pseudarthrosis)
- degenerative disease, including neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability, and
- short term stabilization of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom expectancy is of insufficient duration to permit achievement of fusion.

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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SignatureOrtho™

510(k) SUMMARY

Manufacturer:	Signature Orthopaedics Pty Ltd 7 Sirius Road Lane Cove, NSW 2066 Australia
Device Trade Name:	Freedom™ Posterior Cervical Screw System
Common Name:	Posterior cervical-thoracic system
Contact:	Dr. Declan Brazil Chief Executive Officer
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:	May 1st, 2025
Classification:	Class II per 21 CFR 888.3075: Posterior cervical screw system (NKG)
Predicate Devices:	Substantial equivalence to the following devices is claimed: • Saxxony™ Posterior Cervical Thoracic System (K182508)

Device Description:

The Freedom™ Posterior Cervical Screw System consists of screws, longitudinal rods and cross connectors in a variety of sizes to accommodate differing anatomic requirements. The cervical screws are inserted into adjacent vertebrae, then rods are clamped into the tulip of the pedicle screw using the cap screw, thus immobilising the instrumented vertebrae. The cross-connector may then be attached between rods to improve stability. The system components are made of Ti6Al4V alloy and are supplied sterile.

Indications for Use:

The Signature Orthopaedics Freedom Posterior Cervical Screw System is used to provide immobilization and stabilization of spinal segments (C1 to C7) as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the cervical spine:

- traumatic spinal fractures and/or traumatic dislocations

- instability or deformity; failed previous fusions (e.g. pseudarthrosis)
- degenerative disease, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability, and
- short term stabilization of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom expectancy is of insufficient duration to permit achievement of fusion.

Comparison of Technological Characteristics:

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

- Indications for Use
- Materials of manufacture
- Structure support mechanism
- Principle of operation
- Sizes
- Design

Therefore, the fundamental scientific technology of the Signature Orthopaedics Freedom Posterior Cervical Screw System is the same as the previously cleared predicate.

Performance Testing:

Non-clinical testing and engineering evaluations were conducted to verify that the performance of the Signature Orthopaedics Freedom Posterior Cervical Screw System is adequate for anticipated in-vivo use. The following non-clinical testing was carried out on the worst-case sizes of the subject cervical screws:

- Static and dynamic compression bending testing
- Static torsion testing
- Static Flexion-Extension Moment Test
- Axial Gripping Test
- Axial Torsional Test
- Screw insertion testing
- Screw pull-out testing
- Screw torque to failure testing

Testing was done in accordance with the following testing standards:

- ASTM-F1717_Standard Test Methods for Spinal Implant Construct in a Vertebrectomy Model
- ASTM-F1798_ Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
- ASTM-F543_Standard Specification and Test Method for Metallic Medical Bone Screw

The results of non-clinical testing show that the strength of the Signature Orthoapedics Freedom Posterior Cervical Screw System is sufficient for their intended use and substantially equivalent to the legally marketed predicate device.

Conclusion:

The Freedom™ Posterior Cervical Screw System have the same intended use and same indications for use as the predicate device. The subject devices use the same operating principle, incorporate the same basic design and labelling, and are manufactured and sterilised using the same materials and processes as the predicate device. The subject devices are substantially equivalent to the legally marketed predicate device.