February 6, 2025

Signature Orthopaedic Pty Ltd.
℅ Jared Walkenhorst
Consultant
Novare Medical Consulting
1765 Dusty Boot Drive
Lafayette, Colorado 80026

Re: K241599
Trade/Device Name: Signature Osteosynthesis Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: January 29, 2025
Received: January 29, 2025

Dear Jared Walkenhorst:

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,

Thomas Mcnamara -S

For: Christopher Ferriera, MS
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma 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)*

K241599

Device Name

The Signature Osteosynthesis Plate System

Indications for Use *(Describe)*

The Signature Osteosynthesis Plate System is intended for adult patients for internal fixation and stabilization of fractures, osteotomies, malunions, and non-unions. The 1/3 Tubular Plate and Compression Plate Small are intended for internal fixation and stabilization of fractures, osteotomies, malunions, and non-unions of the Foot, hand, wrist, and forearm. Additionally, the Compression Plate Narrow and Compression Plate Broad are intended for internal fixation and stabilization of fractures, osteotomies, malunions, and non-unions of the upper extremity and lower extremity, except for the femur and proximal tibia. The Clavicle Plates are intended for use in fixation of fractures, osteotomies, and non-unions of the clavicle in adult patients in whom the clavicular growth plates have fused or in whom the growth plates can be crossed by the plate system.

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.

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Sponsor:	Signature Orthopaedic Pty Ltd. 7 Sirius Rd Lane Cove West, NSW 2066 Sydney, Australia
Submitter's Phone:	+61 2 9428 5181
Submitter Contact:	Dr. Declan Brazil declan.brazil@signatureortho.com.au
Contact Person:	Mr. Jared Walkenhorst 720-215-9244 Novare Medical llc, Consultant
Date:	January 29, 2025
Trade Name:	Signature Osteosynthesis Plate System
Classification Product Code:	HRS, HWC
Device Common Name:	Plate, fixation, bone Screw, fixation, bone
Regulation Number / Description:	21 CFR § 888.3030 Single/multiple component metallic bone fixation appliances and accessories 21 CFR § 888.3040 Smooth or threaded metallic bone fixation fastener
Predicate Device(s):	K171320
Device Description:	The Signature Osteosynthesis Plate System utilizes screws and plates of various lengths and designs to accommodate a variety of patient anatomies. The System utilizes medical grade Titanium alloy. System implants are provided both sterile and non-sterile with instructions for steam sterilization. The sterile implants are provided sterilized in Tyvek packaging. The implants are single use only. The Signature Osteosynthesis Plate System instruments are provided non-sterile with instructions for steam sterilization and are reusable.
Intended Use/Indications for use:	The Signature Osteosynthesis Plate System is intended for adult patients for internal fixation and stabilization of fractures, osteotomies, malunions, and non-unions. The 1/3 Tubular Plate and Compression Plate Small are intended for internal fixation and stabilization of fractures, osteotomies, malunions, and non-unions of the Foot, hand, wrist, and forearm. Additionally, the Compression Plate Narrow and Compression Plate Broad are intended for internal fixation and stabilization of fractures, osteotomies, malunions, and non-unions of the upper extremity and lower extremity, except for the femur and proximal tibia. The Clavicle Plates are intended for use in fixation of fractures, osteotomies, and non-unions of the clavicle in adult patients in whom the clavicular growth plates have fused or in whom the growth plates can be crossed by the plate system.

Technological Characteristics Comparison to Predicate Device(s):	The subject and predicate devices 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 • Structural support mechanism • Principle of operation • Sizes
Performance Data (Nonclinical and/or Clinical):	The Signature Osteosynthesis Plate System have been tested in the following test modes: • Static Four-point Bending per ASTM F382-99 (2008) • Dynamic Four-point Bending per ASTM F382-99 (2008) • Static Torsion per ASTM F543-13 • Static Axial Pullout per ASTM F543-13 The results of this non-clinical testing show that the strength of the Signature Osteosynthesis Plate System is sufficient for their intended use and substantially equivalent to legally marketed predicate devices. *Clinical Performance and Conclusions:* Clinical data and conclusions were not needed for this device.
Conclusion:	The subject devices have the same intended use and same indications for use as the predicate devices. The subject devices use the same operating principle, incorporate the same basic design and labeling and are manufactured and sterilized using the same materials and processes as the predicate devices. Any differences do not raise new 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 devices.