May 12, 2025

Signature Orthopaedics Pty Ltd
Samhita Soman
Regulatory Affairs Lead
7 Sirius Road
Lane Cove West, NSW 2066
Australia

Re: K242477
Trade/Device Name: Shoulder Soft Tissue Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: April 10, 2025
Received: April 10, 2025

Dear Samhita Soman:

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,

CHRISTOPHER FERREIRA -S

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)*

K242477

Device Name

Shoulder Soft Tissue Anchors

Indications for Use *(Describe)*

Components of the Signature Orthopaedics range of soft tissue fixation devices are intended to reattach ligament, tendon or soft tissue to bone. Specifically, the BI-ON Screw and Anchor, BI-ON Bio-screw and Bio-anchor, Vector Knotted, ATOK, Vortex Anchor, Dynaloc Anchor and Shoulder Suture Anchor are indicated for use in the shoulder, including:
Shoulder

- Capsular stabilizaton
    - o Bankart Repair
    - o Anterior shoulder instability
    - o SLAP lesion repairs
    - o Capsular shift or capsulolabral reconstructons
- Acromioclavicular separaton repairs
- Deltoid repairs
- Rotator cuff tear repairs
- Biceps tenodesis

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

Manufacturer:	Signature Orthopaedics Pty Ltd 7 Sirius Road Lane Cove, NSW 2066 Australia
Device Trade Name:	Shoulder Soft Tissue Anchors
Common Name:	Soft Tissue Anchor
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:	April 10th, 2025
Classification:	Class II per 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener (MBI)
Predicate Devices:	Substantial equivalence to the following devices is claimed: • Primary Predicate - Smith & Nephew Twinfix Ultra PK Suture Anchor (K152566) • Additional Predicate - Smith & Nephew Bioraptor PK Anchor (K152566) • Additional Predicate - Stryker Knotilus Anchor (K113297) • Additional Predicate - KATOR Suture Anchor (K173269) • Additional Predicate - Smith & Nephew Healicoil PK Suture Anchor (K113294)

Device Description:

The Shoulder Soft Tissue Anchor System consists of a range of implants for soft tissue fixation to bone in the shoulder joint. The soft tissue anchors are manufactured from PEEK OPTIMA LT1 (ASTM F2026) or a PEEK/Hydroxyapatite composite and are available as knotted and knotless variants. Several of the soft tissue anchor variants are supplied pre-loaded with sutures and preassembled onto a driver. The UHMWPE (HS fibre) sutures are finished devices externally supplied by RiverPoint Medical and previously cleared through 510(k) K10006. All components are intended for single use only.

The following variants are included in the range of Shoulder Soft Tissue Anchors:

- Turbine Anchor
- Mini Incision Anchor
- Turbine OP Anchor
- Vortex Anchor
- Vector Anchor
- DynaLoc Anchor
- BI-ON Bio Anchor
- Arthroscopic Transosseous Knotless (ATOK) Anchor

Indications for Use:

Components of the Signature Orthopaedics range of soft tissue fixation devices are intended to reattach ligament, tendon or soft tissue to bone. Specifically, the BI-ON Screw and Anchor, BI-ON Bio-screw and Bio-anchor, Vector Knotted, ATOK, Vortex Anchor, Dynaloc Anchor and Shoulder Suture Anchor are indicated for use in the shoulder, including:

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  o Capsular shift or capsulolabral reconstructons
• Acromioclavicular separaton repairs
• Deltoid repairs
• Rotator cuff tear repairs
• Biceps tenodesis

Comparison of Technological Characteristics:

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
- Structure support mechanism
- Principle of operation
- Sizes

Performance Testing:

The following non-clinical testing was carried out on Signature Orthopaedics Shoulder Soft Tissue Anchor System:

- Anchor insertion testing
- Anchor pull-out testing
- Anchor torque to failure testing
- Anchor fatigue testing

Testing was performed using ASTM F543 as a guide

The results of non-clinical testing show that the strength of the Signature Orthoapedics Shoulder Soft Tissue Anchor System is sufficient for their intended use and substantially equivalent to legally marketed predicate devices.

Conclusion:

The Shoulder Soft Tissue Anchor System 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 labelling, and are manufactured and sterilised 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.