



May 21, 2025

Stryker Endoscopy
Matt Corbett
Staff Regulatory Affairs Specialist
5900 Optical Court
San Jose, California 95138

Re: K250528

Trade/Device Name: Stryker AlphaVent™ Knotless SP Biocomposite Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI, MBI
Dated: February 21, 2025
Received: February 24, 2025

Dear Matt Corbett:

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 Ferreira, M.S.

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

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.

K250528

?

Please provide the device trade name(s).

?

Stryker AlphaVent™ Knotless SP Biocomposite Anchor

Please provide your Indications for Use below.

?

The Stryker AlphaVent™ Knotless SP Biocomposite Anchor is intended to be used for soft-tissue to bone fixation in the shoulder, foot and ankle, knee, hand and wrist, elbow, and hip in skeletally mature pediatric and adult patients. It is indicated for use in the following procedures:

- Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair
- Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Quadriceps Tendon Repair, Secondary or Adjunct Fixation for ACL/PCL Reconstruction or Repair, Meniscal Root Repair, MPFL Repair/Reconstruction
- Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction
- Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Reconstruction, Lateral Epicondylitis Repair
- Hip: Capsular Repair, Acetabular Labral Repair, Gluteus Medius Repair, Proximal Hamstring Repair

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)

?

510(k) Summary - K250528

Submitter:

Applicant	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138
Contact Person	Matt Corbett Staff Regulatory Affairs Specialist Phone: (408) 754-2000 Email: matt.corbett@stryker.com
Date Prepared	February 21 st , 2025

Subject Device:

Name of Device	AlphaVent Knotless SP Biocomposite Anchor
Common or Usual Name	Suture, Fastener, Fixation, Biodegradable, Soft Tissue
Classification Name	Single/Multiple Component Metallic Bone Fixation Appliances and Accessories (21 C.F.R. §888.3030); Smooth or Threaded Metallic Bone Fixation Fastener (21 C.F.R. §888.3040)
Regulatory Class	Class II
Product Code	MAI; MBI

Predicate and Reference Devices:

Name of Device	Primary Predicate – Stryker AlphaVent Knotless SP PEEK Anchor (K233893) (MBI)
	Secondary Predicate – Arthrex SwiveLock Anchor (K203495) (MAI, MBI)
	Reference – Stryker AlphaVent Biocomposite Suture Anchor (K231093) (MAI)

Device Description:

The AlphaVent Knotless SP Biocomposite Anchors (herein referred to as the subject device(s)) are bone anchors with a screw-in mechanism. The subject device is comprised of a poly-ether-ether-ketone (PEEK) eyelet and a biocomposite (Poly-L-lactic Acid (PLLA)/beta-tricalcium phosphate (β -TCP)) anchor body, pre-assembled onto a disposable stainless-steel inserter, which enables insertion of the anchor into bone either via a self-punching mechanism or after creation of a pilot hole. The devices are single use, provided sterile, and are packaged in sterile barrier systems (SBS).

Indications for Use:

The AlphaVent Knotless SP Biocomposite Anchor is intended to be used for soft-tissue to bone fixation in the shoulder, foot and ankle, knee, hand and wrist, elbow, and hip in skeletally mature pediatric and adult patients. It is indicated for use in the following procedures:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Quadriceps Tendon Repair, Secondary or Adjunct Fixation for ACL/PCL Reconstruction or Repair, Meniscal Root Repair, MPFL Repair/Reconstruction

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Reconstruction, Lateral Epicondylitis Repair

Hip: Capsular Repair, Acetabular Labral Repair, Gluteus Medius Repair, Proximal Hamstring Repair

Comparison of Technological Characteristics with the Predicate Device:

The AlphaVent Knotless SP Biocomposite Anchor is a line extension of Predicate A and is identical in terms of design, intended use, indications for use, and implantation technique and equivalent in terms of other technological characteristics and performance attributes . It is identical to Predicate B in terms of in terms of intended use, indications for use, raw material intended for implantation, general anchor system design features. It is equivalent in terms of other technological characteristics and performance attributes. Any minor differences between the subject and predicate devices do not raise new questions of safety or effectiveness. Therefore, based on the criteria described in 21 CFR §807.100, the AlphaVent Knotless SP Biocomposite Anchor is substantially equivalent to the identified predicate devices.

Performance Testing:

Non-clinical benchtop testing was performed to evaluate the performance characteristics of the AlphaVent Knotless SP Biocomposite Anchor, including ultimate tensile strength (UTS) and insertion performance. The proposed device demonstrated statistically equivalent or higher UTS compared to the predicate devices immediately after insertion, following cyclic loading, and after accelerated degradation at multiple time points through the anticipated duration of healing. Additionally, successful insertion was confirmed under worst-case conditions. Bacterial endotoxin testing was also performed on the AlphaVent Knotless SP Biocomposite Anchor, with passing results below the required limits. The results support that the AlphaVent Knotless SP Biocomposite Anchor raises no new questions of safety or effectiveness and is substantially equivalent to the predicate devices.

Conclusions:

The information presented within this Traditional 510(k) demonstrates that the AlphaVent Knotless SP Biocomposite Anchors are substantially equivalent to the predicate devices, and will perform as safely and effectively within the intended use.