August 30, 2023

Stryker Endoscopy
Katie Farraro
Senior Staff Regulatory Affairs Specialist
Stryker Endoscopy
5900 Optical Ct.
San Jose, California 95138

Re: K231093
Trade/Device Name: AlphaVent Suture Anchors
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: July 24, 2023
Received: July 24, 2023

Dear Katie Farraro:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Jesse Muir -S

Jesse Muir, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231093

Device Name

AlphaVent Suture Anchors

Indications for Use *(Describe)*

The AlphaVent Suture Anchors are intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip in skeletally mature pediatric and adult patients for 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 and Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair/Tendon Repair and Bunionectomy

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

Hand and 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, Gluteal Tendon Repair, Proximal Hamstring Repair

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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510(k) Summary

I. SUBMITTER

Stryker Endoscopy
5900 Optical Ct.
San Jose, CA 95138

Contact Person: Katie Farraro, PhD, RAC
Senior Staff Regulatory Affairs Specialist
Phone: 408-754-2285

Date Prepared: April 17, 2023

II. DEVICE

Name of Device:	Stryker AlphaVent Suture Anchors
Common Name:	Fastener, Fixation, Nondegradable, Soft Tissue Fastener, Fixation, Biodegradable, Soft Tissue
Classification Name:	Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040) Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)
Regulatory Class:	II
Product Code:	MBI, MAI

III. PREDICATE AND REFERENCE DEVICES

Predicate A: Stryker AlphaVent PEEK Suture Anchors
Company Name: Stryker
510(k) Number: K211502

Predicate B: Arthrex SwiveLock Anchors
Company Name: Arthrex
510(k) Number: K203495

Reference Device: Stryker Iconix All Suture Anchors
Company Name: Stryker
510(k) Number: K133671

IV. OBJECTIVE

The purpose of this Traditional 510(k) submission is to obtain Food and Drug Administration (FDA) authorization to market modifications to the AlphaVent PEEK Suture Anchors. Specifically, this submission proposes two modifications to Stryker's legally marketed AlphaVent devices: (1) a line extension to introduce new AlphaVent anchor configurations composed of an absorbable material (i.e., "AlphaVent Biocomposite Suture Anchors"), and 2) an expansion in the indications for use to include the

use of the AlphaVent Suture Anchors in skeletally mature pediatric patients, as well as to include two additional surgical procedures: gluteal tendon repair and proximal hamstring repair.

V. DEVICE DESCRIPTION

The AlphaVent Suture Anchors are bone anchors with a screw-in design. Each anchor is vented and cannulated and is provided pre-loaded with one or more working sutures with or without needles. The working sutures run through the cannulated anchor body and are attached to the distal end of the anchor by an integrated suture loop, referred to as a "soft eyelet." The anchor with working sutures is provided pre-assembled on an inserter, which enables insertion of the anchor into bone after creation of a pilot hole. The devices are provided sterile and are packaged in sterile barrier systems (SBS) that include one anchor pre-loaded with suture on an inserter.

VI. INTENDED USE

The AlphaVent Suture Anchors are intended to be used for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip in skeletally mature pediatric and adult patients for 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 and Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair/Tendon Repair and Bunionectomy

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis, Quadriceps Tendon Repair, Secondary or adjunct fixation for ACL/PCL Reconstruction or Repair

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

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

Hip: Capsular Repair, Acetabular Labral Repair, Gluteal Tendon Repair, Proximal Hamstring Repair

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The modified AlphaVent Suture Anchors are identical to Predicate A (AlphaVent PEEK devices) in terms of intended use, operational principle, design, and shelf life, and they are equivalent in terms of sterilization and packaging. They are identical to Predicate B (SwiveLock Anchors) in terms of intended use, general design features, and operational principle, and are equivalent in terms of indications for use, materials intended for implantation, and performance attributes. The minor differences between the modified AlphaVent Suture Anchors and predicate devices do not raise new questions of safety and effectiveness, and these devices are substantially equivalent based on the criteria described in 21 CFR §807.100.

VIII. PERFORMANCE DATA

Non-clinical benchtop testing was conducted to evaluate the performance characteristics of the modified AlphaVent Suture Anchors, including ultimate tensile strength ("UTS") and insertion testing. For the AlphaVent Biocomposite Suture Anchors, UTS testing was also repeated following *in vitro* degradation. The AlphaVent anchors demonstrated equivalent pull-out strength to the Predicate B devices and no new issues of safety and effectiveness were identified. Testing of the *in vitro* degradation rate of the AlphaVent Biocomposite Suture Anchors was also performed.

Biocompatibility testing was performed on the final finished devices per ISO 10993-1:2018 to confirm that the AlphaVent devices met all required biocompatibility testing endpoints. Testing for material-mediated pyrogenicity and bacterial endotoxins was also performed, with passing results below the required limits.

IX. CONCLUSIONS

The information presented within this Traditional premarket submission demonstrates that the modified AlphaVent Suture Anchors are substantially equivalent to the predicate devices and will perform as safely and effectively within the intended use.