August 4, 2021

Stryker Endoscopy
Christie Samsa
Principal Regulatory Affairs Specialist
5900 Optical Ct.
San Jose, California 95138

Re: K211502
Trade/Device Name: Alpha Vent PEEK Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 13, 2021
Received: May 14, 2021

Dear Christie Samsa:

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,

for

Laura C. Rose, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211502

Device Name
AlphaVent PEEK Suture Anchors

Indications for Use *(Describe)*
The AlphaVent PEEK Suture Anchors are intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip 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 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 and Quadriceps Tendon Repair. Secondary or adjunct fixation for ACL/PCL reconstruction or Repair.

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

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

Hip: Capsular Repair, Acetabular Labral 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.

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510(k) Summary

Submitter:

Applicant	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138
Contact Person	Christie Samsa Principal Regulatory Affairs Specialist Phone: (978) 500-1303 Facsimile: (408) 754-2598 Email: christie.samsa@stryker.com
Date Prepared	May 13, 2021

Subject Device:

Name of Device	AlphaVent PEEK Suture Anchor
Common or Usual Name	Suture, Fastener, Fixation, Nondegradable, Soft Tissue
Classification Name	Fastener, Fixation, Nondegradable, Soft Tissue, 21 CFR 888.3040
Regulatory Class	Class II
Product Code	MBI

Predicate Device:

Name of Device	Arthrex Swivelock Anchors, K191226

Note: The predicate device has not been subject to a design-related recall.

Device Description:

The AlphaVent PEEK Suture Anchor (herein referred to as the proposed device(s)) 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 anchors are offered in a poly-ether-ether-keytone (PEEK) material with the integrated suture eyelet offered in non-absorbable USP braided ultra-high molecular weight polyethylene (UHMWPE) high strength suture. The devices are provided sterile and are packaged in sterile barrier systems (SBS) that include one anchor pre-loaded with suture on an inserter.

Indications for Use:

The AlphaVent PEEK Suture Anchors are intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip 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 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 and Quadriceps Tendon Repair. Secondary or adjunct fixation for ACL/PCL reconstruction or Repair.

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

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

Hip: Capsular Repair, Acetabular Labral Repair.

Comparison of Technological Characteristics with the Predicate Device:

Feature	Subject Device (This Submission)	Predicate Device (K191226)
	AlphaVent PEEK Suture Anchor	**Arthrex SwiveLock Suture Anchor**
Intended Use	Fixation of soft tissue to bone	Same as subject device
Indications for Use	The AlphaVent PEEK Suture Anchors are intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip in the following procedures: <u>Shoulder:</u> Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction. <u>Foot and Ankle:</u> Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair/Tendon Repair and Bunionectomy. <u>Knee:</u> Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis and Quadriceps Tendon Repair. Secondary or adjunct fixation for ACL/PCL reconstruction or Repair. <u>Hand/Wrist</u>: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction. <u>Elbow:</u> Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair. <u>Hip:</u> Capsular Repair, Acetabular Labral Repair.	Same as subject device
Operational Principle	Fixation of suture to bone achieved by interference fit with screw-in anchor, suture fixated by eyelet	Fixation of suture to bone achieved by interference fit with sutures and screw-in anchor
Key Patient-Contacing Materials	Material: Poly-ether-ether ketone (PEEK), UHMWPE	Same as subject device
Anchor System Design	Screw in anchor with eyelet Inserter Sutures for fixation	Similar to subject device
Eyelet Design	Integrated Closed eyelet	Separate Closed eyelet

Feature	Subject Device (This Submission)	Predicate Device (K191226)
	AlphaVent PEEK Suture Anchor	**Arthrex SwiveLock Suture Anchor**
Anchor Diameter	4.75mm 5.5mm 6.5mm	3.5mm - 9mm
Sterilization Method, SAL	Ethylene Oxide (EO), SAL: 10^{-6}	Similar to subject device
Packaging	Double Barrier Blister or Pouch Single Use Only	Similar to subject device
Biocompatibility	Device conforms to ISO 10993-1 for patient contact nature and duration	Similar to subject device

Performance Testing:

Non-clinical benchtop testing was performed to evaluate the performance characteristics of the Stryker AlphaVent PEEK Suture Anchor, including ultimate tensile strength (UTS) and insertion testing. The proposed devices demonstrated similar or increased pull-out strength to the predicate devices, and no new issues of safety and effectiveness were identified. The shelf life of the device is 2 years. Additionally, bacterial endotoxin testing was performed and results of testing met the acceptance criteria.

Conclusions:

The AlphaVent PEEK Suture Anchor is substantially equivalent in design, intended use, principles of operation, technological characteristics and safety features to the predicate device. There are no new issues of safety and/or effectiveness introduced by the AlphaVent PEEK Suture Anchor when used as instructed.