October 24, 2023

Stryker Endoscopy
Madison Mutchler
Senior Regulatory Affairs Specialist
5900 Optical Ct.
San Jose, California 95138

Re: K232683
Trade/Device Name: Knotilus+ PEEK Knotless Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: August 31, 2023
Received: September 1, 2023

Dear Madison Mutchler:

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.

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,

Jesse Muir -S

Digitally signed by Jesse Muir -S
Date: 2023.10.24 14:07:59 -04'00'

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.*

Submission Number *(if known)*

K232683

Device Name

Knotilus+ PEEK Knotless Anchor

Indications for Use *(Describe)*

Indications for Use:

The Knotilus+ PEEK Knotless 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:

2.4x11.3mm, 2.9x12.5mm, and 2.9x15.5mm:
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 and Tendon Repair
Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
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: Acetabular Labral Repair

2.4x8.9mm:
Hip: 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.**

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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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

510(k) Summary

**Submitter:**

| | |
|---|---|
| Applicant | Stryker Endoscopy<br>5900 Optical Court<br>San Jose, CA 95138 |
| Contact Person | Madison Mutchler<br>Senior Regulatory Affairs Specialist<br>Phone: (408) 754-2000<br>Email: madison.mutchler@stryker.com |
| Date Prepared | August 31, 2023 |

**Subject Device:**

| | |
|---|---|
| Name of Device | Knotilus+ PEEK Knotless 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 and Reference Devices:**

| | |
|---|---|
| Name of Device | Predicate - Arthrex PushLock Anchors, K101679 |
| | Predicate - Arthrex Short Suture Anchors, K151092 |
| | Reference - Stryker 3.9MM ReelX STT Suture Anchor System, K120824 |
| | Reference - Stryker AlphaVent Suture Anchors, K231093 |

**Device Description:**
The Knotilus+ PEEK Knotless Anchors (herein referred to as the subject device(s)) are bone anchors with a push-in mechanism. The subject device system is comprised of a poly-ether-ether-ketone (PEEK) eyelet and anchor, pre-assembled onto a disposable stainless-steel inserter, which enables insertion of the anchor into bone after creation of a pilot hole. The devices are single use, provided sterile, and are packaged in sterile barrier systems (SBS).

**Intended Use:**
The Knotilus+ PEEK Knotless 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:

*2.4x11.3mm, 2.9x12.5mm, and 2.9x15.5mm:*
Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift, Capsulolabral Reconstruction
Foot and Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament and Tendon Repair
Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon

Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
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: Acetabular Labral Repair

*2.4x8.9mm:*
Hip: Acetabular Labral Repair

**Comparison of Technological Characteristics with the Predicate Device:**
The Knotilus+ PEEK Knotless Anchor is equivalent to the predicate devices in terms of intended use, indications for use, raw material intended for implantation, general anchor system design features, and operational principle. It is equivalent in terms of other technological characteristics and performance attributes. Any minor differences between the proposed and predicate device 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.

**Performance Testing:**
Non-clinical benchtop testing was performed to evaluate the performance characteristics of the Knotilus+ PEEK Knotless Anchor, including ultimate tensile strength (UTS) and insertion testing. The proposed devices demonstrated higher pull-out strength as compared to the predicate devices as well as successful insertion, and no new issues of safety and effectiveness were identified.

Bacterial endotoxin testing was performed on the Knotilus+ PEEK Knotless Anchor, with passing results below the required limits.

**Conclusions:**
The information presented within this Traditional 510(k) demonstrates that the Knotilus+ PEEK Knotless Anchor is substantially equivalent to the predicate devices, and will perform as safely and effectively within the intended use.