July 23, 2018

Stryker
Katie Farraro
Senior Regulatory Affairs Specialist
5900 Optical Court
San Jose, California 95138

Re: K181083
Trade/Device Name: Stryker All-PEEK Knotless Anchor System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: April 23, 2018
Received: April 24, 2018

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurence D. Coyne -S

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K181083

Device Name
Stryker All-PEEK Knotless Anchor System

Indications for Use *(Describe)*
The Stryker All-PEEK Knotless Anchor System is intended to be used for soft-tissue to bone fixation in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip.

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 and Bunionectomy

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Secondary 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 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

I. SUBMITTER

Stryker Endoscopy
5900 Optical Ct
San Jose, CA 95138

Contact Person: Katie Farraro, Senior Regulatory Affairs Specialist
Phone: 408-754-2285
Fax: 408-754-2507

Date Prepared: June 22, 2018

II. DEVICE

Name of Device:	Stryker All-PEEK Knotless Anchor System
Common or Usual Name:	Suture, Fastener, Fixation, Nondegradable, Soft Tissue
Classification Name:	Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)
Regulatory Class:	II
Product Code:	MBI

III. PREDICATE AND REFERENCE DEVICE

Predicate Device: Arthrex SwiveLock Anchors
Company Name: Arthrex
510(k) Number: K151342

Reference Device: Stryker ReelX STT Suture Anchor System
Company Name: Stryker
510(k) Number: K120824

There has been one Class II recall for the predicate device due to eyelet breakage during insertion of six product configurations. The recall was initiated by the firm in March 2017.

There have been no design-related recalls for the reference device.

IV. DEVICE DESCRIPTION

The Stryker All-PEEK Knotless Anchor System (herein referred to as the proposed device(s)) consists of poly-ether-ether-ketone (PEEK) cannulated screws with a separate

eyelet. The anchor system is designed for insertion of the eyelet and screw into bone either directly or by using instrumentation for creation of a pilot hole. Alternatively, screws may be used without the eyelet for suture fixation in a pre-drilled pilot hole by means of a cannulated screwdriver. Screws and eyelets may be provided either pre-loaded on respective disposable screwdrivers and inserters, or separately for manual loading. A suture threader is included with the eyelet inserter to facilitate loading of suture through the eyelet. Anchor systems are provided sterile and are packaged in single-use sterile barrier systems (SBS) that include one or more screws with or without eyelets.

V. INTENDED USE

The Stryker All-PEEK Knotless Anchor System is intended to be used for soft-tissue to bone fixation in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip.

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

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Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Secondary 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 Reconstruction, Lateral Epicondylitis Repair

Hip: Capsular Repair, Acetabular Labral Repair

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed All-PEEK Knotless Anchor System is identical to the predicate device 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. The 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.

VII. PERFORMANCE DATA

Non-clinical benchtop testing was performed to evaluate the performance characteristics of the Stryker All-PEEK Knotless Anchor System, including ultimate tensile strength (UTS) and insertion testing. The proposed devices demonstrated equivalent or higher pull-out strength to the predicate devices, and no new issues of safety and effectiveness were identified.

Testing was also performed on the final finished devices for material-mediated pyrogenicity and bacterial endotoxins, with passing results below the required limits.

VIII. CONCLUSIONS

The information presented within this traditional premarket submission demonstrates that the Stryker All-PEEK Knotless Anchor System is substantially equivalent to the predicate device and will perform as safely and effectively within the intended use.