November 13, 2020

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

Re: K202355
Trade/Device Name: Stryker Omega 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: August 18, 2020
Received: August 19, 2020

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,

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

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2020

510(k) Number *(if known)*

K202355

Device Name

Stryker Omega PEEK Knotless Anchor System

Indications for Use *(Describe)*

The Stryker Omega 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, Meniscal Root 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: Capular 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, PhD, RAC
Staff Regulatory Affairs Specialist
Phone: 408-754-2285

Date Prepared: August 18, 2020

II. DEVICE

Name of Device: Stryker Omega PEEK Knotless Anchor System
Common 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 DEVICE

Predicate A (Primary Predicate): Stryker All-PEEK Knotless Anchor System
Company Name: Stryker
510(k) Number: K181083

Predicate B: Arthrex SwiveLock C Anchors
Company Name: Arthrex
510(k) Number: K173845

IV. OBJECTIVE

The purpose of this Traditional 510(k) submission is to obtain Food and Drug Administration (FDA) authorization to market a modified Omega PEEK Knotless Anchor System. Specifically, this submission proposes two unrelated modifications to Stryker's legally marketed Omega system: 1) a modification to the anchor system's eyelet, and 2) an expansion in the indications for use to include meniscal root repair.

V. DEVICE DESCRIPTION

The Stryker Omega PEEK Knotless Anchor System consists of poly-ether-ether-ketone ("PEEK") cannulated screws with a separate PEEK 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 preloaded 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.

VI. INTENDED USE

The Stryker Omega 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, Meniscal Root 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

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The modified Omega PEEK Knotless Anchor System is identical to Predicate A (original Omega system) in terms of intended use, geometric design, operational principle, sterilization method, packaging, and shelf life. It is identical to Predicate B (SwiveLock C Anchors) in terms of intended use, indications for use, general design features, and operational principle. It is equivalent to both predicate devices in terms of materials intended for implantation and performance attributes. The minor differences between the modified Omega system 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 Stryker Omega PEEK Knotless Anchor System. Ultimate tensile strength (UTS) and insertion testing were performed to assess the proposed eyelet modification, and cyclic displacement testing was performed to demonstrate that the displacement of the modified Omega anchors is within a clinically-

acceptable range for meniscal root repair. The modified Omega anchors demonstrated equivalent pull-out strength to the Predicate A devices and equivalent displacement to the Predicate B devices, and no new issues of safety and effectiveness were identified.

Biocompatibility testing was performed on the final finished devices per ISO 10993-1:2018 to confirm that the modified Omega system 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 Stryker Omega PEEK Knotless Anchor System is substantially equivalent to the predicate devices and will perform as safely and effectively within the intended use.