March 7, 2024

Stryker Endoscopy
Matt Corbett
Staff Regulatory Affairs Specialist
5900 Optical Ct
San Jose, California 95138

Re: K240407
Trade/Device Name: ICONIX All-Suture Anchor; ICONIX TT All-Suture Anchor; ICONIX with Needles All-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: February 9, 2024
Received: February 9, 2024

Dear Matt Corbett:

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,

Sara S. Thompson -S

For

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)*

K240407

Device Name

ICONIX All-Suture Anchor;
ICONIX TT All-Suture Anchor;
ICONIX with Needles All-Suture Anchor

Indications for Use *(Describe)*

The Stryker ICONIX anchors are intended to be used for soft-tissue to bone fixation in the foot, ankle, knee, hip, hand, wrist, elbow and shoulder. Specific indications are listed below.

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Repair.

Hand/Wrist: Scaphulolunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/ Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, Digital Tendon Repair.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus Reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction.

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis, Medial Patellofemoral Ligament (MPFL) Repair/Reconstruction, Quadriceps Tendon Repair.

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

The Stryker ICONIX Anchors are intended for single use only.

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.

510(k) Summary

Submitter:

Applicant	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138
Contact Person	Matt Corbett Staff Regulatory Affairs Specialist Phone: (408) 754-2000 Email: matt.corbett@stryker.com
Date Prepared	February 9th, 2024

Subject Device:

Device Name(s):	ICONIX, ICONIX TT, ICONIX with Needles All-Suture Anchors
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:

Device Name(s):	Predicates: ICONIX (K133671), ICONIX TT (K170098), ICONIX with Needles All-Suture Anchors (K151201/K173074); All devices are legally manufactured by Stryker Endoscopy
	References: Iconix Anchor (K233468), Iconix Knotless Anchor (K231278); Both devices are legally manufactured by Riverpoint Medical, LLC.

Objective:

By submission of this Bundled Special Premarket Notification, Stryker Endoscopy is requesting clearance to expand the indications of the ICONIX All-Suture Anchor devices by adding three surgical procedures: medial patellofemoral ligament (MPFL) repair/reconstruction, quadriceps tendon repair, and proximal hamstring repair.

Device Description:

The ICONIX Anchors, ICONIX TT Anchors, and ICONIX Anchors with Needles are soft tissue fixation devices with a push-in design, provided preloaded on a disposable inserter. ICONIX Anchors with Needles have needles attached to the free ends of all working sutures. All of the ICONIX All-Suture Anchors are composed of a sheath structure that contains one or more working sutures. The sheath bunches as the anchor is deployed to fixate in bone. Once the anchor has been inserted in the bone, the working sutures are used to complete the soft tissue repair or reconstruction procedure, in accordance with the surgeon's preferred technique for procedures within the indications for use.

Indications for Use:

The Stryker ICONIX anchors are intended to be used for soft-tissue to bone fixation in the foot, ankle, knee, hip, hand, wrist, elbow and shoulder. Specific indications are listed below.

• Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.
• Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Repair.
• Hand/Wrist: Scaphulolunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, Digital Tendon Repair.
• Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus Reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction.
• Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis, Medial Patellofemoral Ligament (MPFL) Repair/Reconstruction, Quadriceps Tendon Repair.
• Hip: Capsular Repair, Acetabular Labral Repair, Gluteal Tendon Repair, Proximal Hamstring Repair.

The Stryker ICONIX Anchors are intended for single use only.

Comparison of Technological Characteristics with the Predicate Device:

The modified ICONIX All-Suture Anchors are identical to the predicate devices in terms of intended use, operational principle, design, shelf life, sterilization, biocompatibility, and performance attributes. They are equivalent in terms of indications for use. The minor differences between the modified ICONIX 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.

Performance Data:

Non-clinical performance testing was previously performed on the ICONIX All-Suture Anchors, in accordance with the FDA Guidance Document, *"Bone Anchors - Premarket Notification (510(k)) Submissions Guidance for Industry and Food and Drug Administration Staff"* (2020). For the proposed expanded indications, as there were no new risks or significantly modified risks requiring new risk control measures, no design changes nor procedural modifications, and no new functional performance requirements, new verification and/or validation activities were not required. Results from the devices' previous verification testing activities remains applicable to demonstrate that the modified devices meet all of the applicable requirements and specifications.

Conclusions:

The assessment presented in this submission establishes the substantial equivalence of the modified ICONIX All-Suture Anchors with expanded indications, including MPFL repair/reconstruction, quadriceps tendon repair, and proximal hamstring repair, to the legally marketed predicate devices. Stryker has demonstrated substantial equivalence, with minor differences that do not raise new questions of safety and effectiveness. As there are no other changes proposed in this 510(k), all other characteristics, including the intended use, procedural steps for use of the devices, technological characteristics, and performance remain identical to those of the predicate devices. In conclusion, the ICONIX All-Suture Anchors with expanded indications are as safe and effective as the legally marketed predicate devices based on the criteria described in 21 CFR §807.100.