DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 31, 2017

Stryker Endoscopy
Mr. Taylor White
Senior Regulatory Affairs Specialist
5670 Greenwood Plaza Blvd., Suite 200
Greenwood Village, Colorado 80111

Re: K170098
Trade/Device Name: ICONIX TT 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: March 6, 2017
Received: March 7, 2017

Dear Mr. White:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170098

Device Name
Stryker ICONIX TT All Suture Anchor

Indications for Use *(Describe)*

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, Iliotibial Band Tenodesis

Hip: Capsular Repair, Acetabular Labral Repair, Gluteal Tendon Repair

The ICONIX TT All Suture 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

I. SUBMITTER

Stryker Endoscopy
5900 Optical Ct
San Jose, CA 95138

Contact Person: Taylor White, Senior Regulatory Affairs Specialist
Phone: 303-336-7285
Fax: 303-993-6195

Date Prepared: February 16, 2017

II. DEVICE

Name of Device:	Stryker ICONIX TT All Suture Anchor Model Numbers: 3910-500-312, 3910-500-322
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 DEVICES

Predicate Device:
Stryker ICONIX All Suture Anchors, K133671
This predicate has not been subject to a design-related recall.

Reference Device: XBraid TT Suture Tape, K162310
This device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Stryker ICONIX TT All Suture Anchors are a line extension of the legally marketed Stryker ICONIX All Suture Anchors. The ICONIX TT All Suture Anchors are soft-tissue fixation devices with a push-in design, provided preloaded on a disposable inserter. They 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.

The Stryker ICONIX TT All Suture Anchors are intended to be used for soft-tissue to bone fixation in the foot, ankle, knee, hip, wrist, elbow, and shoulder. See indications below.

V. INDICATIONS FOR USE

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, Iliotibial Band Tenodesis

Hip: Capsular Repair, Acetabular Labral Repair, Gluteal Tendon Repair

The ICONIX TT All Suture Anchors are intended for single use only.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The intent of this premarket submission is to expand the ICONIX All Suture Anchor product line to include anchor devices that feature flat working sutures. The dimensions and colorant of the sutures have been modified, and associated manufacturing processes have been modified from the predicate device. All materials used in the construction of the proposed device have been shown to be biologically safe. All device modifications have been assessed through thorough risk analysis, and where necessary, verification and validation activities were performed. These activities did not raise new questions of safety or effectiveness. Given this, the proposed ICONIX TT All Suture Anchor products are substantially equivalent to the legally marketed predicate device in regard to intended use, fundamental scientific technology, operational principles, and performance attributes.

VII. PERFORMANCE DATA

Non-clinical verification and validation testing was performed to assess the efficacy of the proposed Stryker ICONIX TT All Suture Anchors as compared to the predicate device. This testing included inserter removal force, extension during cyclic loading, ultimate tensile strength following cyclic loading, ultimate tensile strength, angled insertion, design validation, packaging validation, sterilization validation, and biocompatibility testing. The ICONIX TT All Suture Anchors have been evaluated to be non-pyrogenic.

The results of all testing demonstrate that the ICONIX TT anchors are substantially equivalent to the predicate device. Clinical testing was not required to demonstrate substantial equivalence for this submission.

VIII. CONCLUSIONS

The information presented within this special premarket submission demonstrates that Stryker ICONIX TT All Suture Anchors are substantially equivalent to the predicate device.