Stryker
Jacob Scheenstra
Senior Regulatory Affairs Specialist
5670 Greenwood Plaza Boulevard, Suite 200
Greenwood Village, Colorado 80111

April 4, 2018

Re: K173074
Trade/Device Name: ICONIX XBraid TT with Needles, NanoTack TT 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 5, 2018
Received: March 6, 2018

Dear Mr. Scheenstra:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173074

Device Name
ICONIX XBraid TT with Needles

Indications for Use *(Describe)*
The Stryker ICONIX XBraid TT with Needles devices are intended to be used for soft-tissue to bone fixation in the foot, ankle, knee, hip, wrist, elbow, and shoulder. See indications 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 Joint 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

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:

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Food and Drug Administration
Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

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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)*
K173074

Device Name
NanoTack TT Suture Anchor

Indications for Use *(Describe)*

The NanoTack TT Suture Anchor is intended for the fixation of soft tissue to bone in the hip, shoulder, foot/ankle, hand/wrist, elbow, and knee in the following procedures:

Hip: Hip capsule repair, acetabular labrum reattachment

Shoulder: Capsular stabilization (Bankart repair, anterior shoulder instability, SLAP lesion repair, capsular shifts or capsulolabral reconstructions), acromioclavicular separation repair, deltoid repair, rotator cuff tear repair, biceps tenodesis

Foot and Ankle: Hallux valgus repair, Medial or lateral instability repair/reconstruction, Achilles tendon repair/reconstruction, midfoot reconstruction, Metatarsal ligament/tendon repair/reconstructions, bunionectomy

Elbow, Wrist, and Hand: Biceps tendon reattachment, ulnar or radial collateral ligament reconstruction, Lateral epicondylitis repair

Knee: Extra-capsular repair (medial collateral ligament, lateral collateral ligament, posterior oblique ligament), patellar realignment and tendon repairs (vastus medialis obliquous advancement), Iliotibial band tenodesis

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)

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510(k) Summary

I. SUBMITTER

Stryker Endoscopy
5900 Optical Ct
San Jose, CA 95138

Contact Person: Jacob Scheenstra, Sr. Regulatory Affairs Specialist
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Email: jacob.scheenstra@stryker.com

Date Prepared: April 2, 2018

II. DEVICE

This is a bundled 510(k) submission including information regarding a change that is impacting two product lines, referred to as Proposed Device A and B.

Proposed Device A: Stryker ICONIX XBraid TT with Needles
Model Numbers: 3910-500-212, 3910-500-222
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

Proposed Device B: NanoTack TT Suture Anchor
Model Number: 00CAT02969
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 A: Stryker ICONIX with Needles, K151201
This predicate has not been subject to a design-related recall.

Predicate Device B: NanoTack Suture Anchor 1.4 mm, K131769
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

Stryker ICONIX XBraid TT with Needles

The ICONIX XBraid TT with Needles devices are a line extension of the legally marketed Stryker ICONIX with Needles products. The ICONIX XBraid TT with Needles devices are soft-tissue fixation devices consisting of an all suture anchor with a push-in design, preloaded on a disposable inserter. The anchors consist of a polyester sheath interwoven over non-absorbable working sutures. Fixation is achieved by the polyester sheath bunching when the anchor is deployed. The suture "tape" is composed of 100% ultra-high molecular weight polyethylene (UHMWPE). These devices include needles, which are housed in a compartment within the inserter handle. These needles are swaged to the free ends of all working sutures for use at the discretion of the surgeon. The devices are provided in a sterile state; the anchor and inserter assembly will be packaged in a single-use sterile barrier system (SBS) containing a disposable drill and drill guide to aid in bone hole creation and anchor implantation.

There are two proposed configurations of The ICONIX XBraid TT with Needles device:

- 1.4mm suture anchor with 1.2mm XBraid TT suture tape, and
- 2.3mm suture anchor with 2.0mm XBraid TT suture tape.

NanoTack TT Suture Anchor

The NanoTack TT Suture Anchor is a line extension of the legally marketed NanoTack Suture Anchor. The NanoTack TT Suture Anchor is a non-degradable implant device consisting of a suture anchor with attached non-degradable, flat suture tape preassembled on an insertion device. This device is provided sterile, and is intended for single use only. The anchor is manufactured from polyether ether ketone (PEEK), and the suture tape is composed of 100% ultra-high molecular weight polyethylene (UHMWPE). The anchor and inserter assembly will be packaged in a single-use sterile barrier system (SBS).

There is one proposed configuration of the NanoTack TT Suture Anchor:

- 1.4mm anchor with 1.2mm XBraid TT suture tape.

V. INTENDED USE

The Stryker ICONIX XBraid TT with Needles

The Stryker ICONIX XBraid TT with Needles devices are intended to be used for soft-tissue to bone fixation in the foot, ankle, knee, hip, wrist, elbow, and shoulder. See indications 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 Joint 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

NanoTack TT Suture Anchor

The NanoTack TT Suture Anchor is intended for the fixation of soft tissue to bone in the hip, shoulder, foot/ankle, hand/wrist, elbow, and knee in the following procedures:

Hip: Hip capsule repair, acetabular labrum reattachment

Shoulder: Capsular stabilization (Bankart repair, anterior shoulder instability, SLAP lesion repair, capsular shifts or capsulolabral reconstructions), acromioclavicular separation repair, deltoid repair, rotator cuff tear repair, biceps tenodesis

Foot and Ankle: Hallux valgus repair, Medial or lateral instability repair/reconstruction, Achilles tendon repair/reconstruction, midfoot reconstruction, Metatarsal ligament/tendon repair/reconstructions, bunionectomy

Elbow, Wrist, and Hand: Biceps tendon reattachment, ulnar or radial collateral ligament reconstruction, Lateral epicondylitis repair

Knee: Extra-capsular repair (medial collateral ligament, lateral collateral ligament, posterior oblique ligament), patellar realignment and tendon repairs (vastus medialis obliquous advancement), Iliotibial band tenodesis

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The intent of this bundled premarket submission is to expand the ICONIX with Needles and NanoTack Suture Anchor product lines to include anchor devices that feature flat working sutures. Both product lines will undergo changes identical in nature. Each product line has its own respective predicate device for the purposes of this submission.

For both product lines, the dimensions and colorant of the sutures have been modified, and associated manufacturing processes have been modified relative to the respective predicate devices. All materials used in the construction of the proposed devices 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 XBraid TT with Needles devices are substantially equivalent to the respective legally marketed predicate device in regard to intended use, fundamental scientific technology, operational principles, and performance attributes. Similarly, the proposed NanoTack TT Suture Anchor product is substantially equivalent to the legally marketed predicate device in regard to intended use, fundamental scientific technology, operational principles, and performance attributes.

VII. PERFORMANCE DATA

A risk assessment was completed for the proposed device modifications, and non-clinical verification and validation testing was performed to assess the efficacy of the proposed Stryker ICONIX XBraid TT with Needles devices and NanoTack TT Suture Anchor devices as compared to the respective predicate devices.

The following evaluations were considered as part of the risk assessments for both devices:

- For ICONIX XBraid TT with Needles, this testing included inserter removal effort, needle removal force, extension during cyclic loading, ultimate tensile strength following cyclic loading, ultimate tensile strength, insertion effort, suture sliding force, design validation, packaging validation, sterilization validation, and biocompatibility evaluation.

- For NanoTack TT Suture Anchor, the testing included deployment force, suture sliding force, ultimate tensile strength, insertion effort, a suture snagging test, design validation, packaging validation, sterilization validation, and a biocompatibility evaluation.

Pyrogen testing was also completed for the proposed ICONIX XBraid TT with Needles device and NanoTack TT Suture Anchor device. This testing demonstrated that both of the proposed devices meet the recommended pyrogen limits.

The results of all testing demonstrate that the proposed ICONIX XBraid TT with Needles and NanoTack TT Suture Anchor devices are substantially equivalent to the respective predicate devices. Clinical testing was not required to demonstrate substantial equivalence for this submission.

VIII. CONCLUSIONS

The information presented within this special premarket submission demonstrates that the Stryker ICONIX XBraid TT with Needles and the NanoTack TT Suture Anchor devices are substantially equivalent to the respective predicate devices.