



Food and Drug Administration  
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Stryker  
Katie Farraro  
Regulatory Affairs Specialist  
5900 Optical Court  
San Jose, California 95138

August 24, 2017

Re: K171465

Trade/Device Name: Stryker Self-Punching ICONIX  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: Class II  
Product Code: MBI  
Dated: July 7, 2017  
Received: July 10, 2017

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.

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)  
K171465

Device Name  
Stryker Self-Punching ICONIX

Indications for Use (Describe)

The Stryker Self-Punching ICONIX Anchors are intended to be used for soft tissue-to-bone fixation in the elbow, shoulder, knee, and hip. 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

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.**

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## **510(k) Summary**

### **I. SUBMITTER**

Stryker Endoscopy  
5900 Optical Ct  
San Jose, CA 95138

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

Date Prepared: July 7, 2017

### **II. DEVICE**

Name of Device: Stryker Self-Punching ICONIX  
Model Numbers: 3910-500-921, 3910-500-922  
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 Devices:

Predicate A (Primary Predicate):  
Device Name: ICONIX All Suture Anchors  
Company Name: Stryker  
510(k) #: K133671

Predicate B:  
Device Name: Y-Knot RC All-Suture Anchor, 2.8mm - Double Loaded and Triple Loaded w/ #2 Hi-Fi Sutures  
Company Name: ConMed Corporation  
510(k) #: K133224

Predicate devices have not been subject to a recall.

Reference Devices:

Reference Device 1

Device Name: Stryker ICONIX TT All Suture Anchor  
Company Name: Stryker  
510(k) #: K170098

Reference Device 2

Device Name: Force Fiber Polyethylene Non-Absorbable Suture  
Company Name: Teleflex Medical  
510(k) #: K063778

Reference Device 3

Device Name: Force Fiber Blue Polyethylene Non-Absorbable Surgical Suture  
Company Name: Beere Precision Medical Instruments, Kmedic, Telef  
510(k) #: K092533

Reference Device 4

Device Name: XBraid TT Suture Tape  
Company Name: Stryker  
510(k) #: K162310

Reference devices have not been subject to a recall.

#### **IV. DEVICE DESCRIPTION**

The Self-Punching ICONIX Anchors (herein referred to as the proposed device(s)) are all suture anchors with a push-in design, provided sterile and preloaded on a disposable inserter. The anchors consist of a polyester sheath interwoven over non-absorbable working sutures, which are folded over and mounted on the forked tip of the inserter. The anchor is inserted into the bone using a self-punching mechanism, and the polyester sheath bunches as the anchor is deployed to allow for fixation in bone. The anchor preloaded on the inserter is packaged in a single-use sterile barrier system (SBS).

#### **V. INTENDED USE**

The Stryker Self-Punching ICONIX Anchors are intended to be used for soft-tissue to bone fixation in the elbow, shoulder, knee and hip. 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

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

## **VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE AND REFERENCE DEVICES**

The Self-Punching ICONIX Anchors are substantially equivalent to Predicate A (the Primary Predicate) with regard to intended use, materials of construct, anchor design and deployment method, and performance attributes.

The proposed devices are substantially equivalent to Predicate B in regard to operational principle (specifically, insertion method). The Self-Punching ICONIX products utilize a self-punching insertion mechanism, such that the device can be directly inserted into bone without the use of a drill or guide.

Reference Devices 1-4 were selected to support scientific methodology throughout this submission, as these legally marketed devices utilize identical components to the proposed devices. Reference Device 1 is another suture anchor in the ICONIX product family that utilizes identical suture tape (XBraid TT) material and anchor sheath material, and Reference Devices 2-4 represent each of the suture components used in the proposed devices as standalone medical devices.

The differences between the proposed products and the predicate devices are summarized below, and do not raise new questions of safety and effectiveness.

Proposed and Predicate Device Differences:

### *Suture Configurations*

The proposed devices include 2.3mm diameter polyester sheaths that are identical to the 2.3mm anchors of Predicate A. However, another suture configuration is available in the proposed devices that includes flat sutures woven into the sheath. This configuration is unique compared to Predicate A.

### *Inserters*

In order to achieve the self-punching insertion mechanism, the inserter of Predicate A has been modified to include a larger diameter, sharper tips, and a longer handle. The

working length of the inserter shaft also features an increased shaft diameter compared to Predicate B.

## **VII. PERFORMANCE DATA**

Non-clinical benchtop testing was performed to verify the fixation strength at time zero as well as following cyclic loading of the Self-Punching ICONIX products. This fixation strength was compared to that of Predicate A through statistical analysis. The comparison indicates that the proposed devices provide statistically higher fixation strength than the devices of Predicate A, and will be functional within the intended use.

Benchtop testing was also performed to verify the insertion effort required for use of the Self-Punching ICONIX products. Due to the equivalent self-punching insertion mechanism, this was compared to that of Predicate B. The comparison indicates that the proposed devices require reduced insertion effort compared to the devices of Predicate B, and will be functional within the intended use.

Clinical testing was not required to demonstrate substantial equivalence for this submission.

## **VIII. CONCLUSIONS**

The information presented within this traditional premarket submission demonstrates that the Stryker Self-Punching ICONIX products are substantially equivalent to the predicate devices and will perform safely and effectively within the intended use.