



Food and Drug Administration  
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June 29, 2015

Stryker Endoscopy  
Ms. Taylor White  
Regulatory Affairs Analyst  
5670 Greenwood Plaza Boulevard, Suite 200  
Greenwood Village, Colorado 80111

Re: K151201

Trade/Device Name: Stryker ICONIX with Needles  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: Class II  
Product Code: MBI  
Dated: May 4, 2015  
Received: May 5, 2015

Dear Ms. 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 yours,

**Lori A. Wiggins -S**

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K151201

Device Name  
Stryker ICONIX with Needles

### Indications for Use (Describe)

The Stryker ICONIX with Needles 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.

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.

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## 510(k) Summary

### **I. SUBMITTER**

Stryker Endoscopy  
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Contact Person: Taylor White, Regulatory Affairs Analyst  
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Date Prepared: June 23, 2015

### **II. DEVICE**

Name of Device: Stryker ICONIX with Needles  
Model Numbers: 3910-500-412, 3910-500-422, 3910-500-425  
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 DEVICES**

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

Predicate B:  
Stryker PEEK and Titanium Soft Eyelet Anchors, K071157  
This predicate has not been subject to a design-related recall regarding the components of interest.

### **IV. DEVICE DESCRIPTION**

ICONIX with Needles (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. Needles are housed in a compartment within the inserter handle and are swaged to the free ends of all working sutures. Fixation is achieved by the polyester sheath bunching when the anchor is deployed. The inserter handle will contain needles for use at the surgeon's discretion. The anchor and inserter will be packaged in a single-use sterile barrier system (SBS) containing a disposable drill and drill guide to aid in anchor implantation.

## **V. INTENDED USE**

The Stryker ICONIX with Needles 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.

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

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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 DEVICES**

The ICONIX with Needles products are substantially equivalent to both Predicate A and Predicate B in regard to intended use. The proposed devices are substantially equivalent to Predicate A (the Primary Predicate) with regard to indications for use, operational principles, materials intended for implantation, and performance attributes. The performance of the proposed devices has been shown to be statistically equivalent to Predicate A.

The proposed devices are substantially equivalent to Predicate B in regard to intended use. Predicate B incorporates identical needles to the proposed 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:

##### *Components Included in Product*

The ICONIX with Needles products are single-use, sterile barrier system (SBS) kits that contain the anchor preloaded on the inserter, a disposable drill, and a disposable drill guide. Predicates A and B include only the anchor preloaded on the inserter.

##### *Anchor Geometry*

The smallest ICONIX with Needles anchor is shorter in length than the smallest anchor of Predicate A. Both anchors require a 1.4mm pilot hole to be drilled, however the anchor of the proposed devices is 8mm in length as compared to the smallest anchor of Predicate A that is 12mm in length. Benchtop testing demonstrated that the smaller proposed devices have equivalent fixation strength to Predicate A. The 2.3mm anchors of the proposed devices are identical to those of Predicate A. See Section 18 for in-depth statistical analysis of this testing.

##### *Needles*

The proposed devices include an openable inserter handle that houses needles swaged to the working sutures. The needles may be used at the discretion of the surgeon, but are not necessary for anchor implantation. Predicate B has been identified because this predicate contains identical needles to those of the proposed devices. The needles are retained in a small foam insert for user safety and ease of use.

## **VII. PERFORMANCE DATA**

Non-clinical benchtop testing was performed to verify the fixation strength following cyclical loading of the ICONIX with Needles products. This fixation strength was compared to that of Predicate A through statistical analysis. The comparison indicates that the proposed devices provide equivalent fixation strength to the devices of Predicate A, 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 Stryker ICONIX with Needles products are substantially equivalent to the predicate devices and will perform safely and effectively within the intended use.