



Food and Drug Administration  
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August 13, 2015

Stryker Endoscopy  
Taylor White  
Regulatory Affairs Analyst  
5900 Optical Court  
San Jose, California 95138

Re: K150584

Trade/Device Name: Stryker Suture Tape  
Regulation Number: 21 CFR 878.5000  
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture  
Regulatory Class: Class II  
Product Code: GAT  
Dated: July 15, 2015  
Received: July 16, 2015

Dear 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" (21CFR 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,

**David Krause -S**

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K150584

Device Name

Stryker Suture Tape

Indications for Use (Describe)

Stryker Suture Tape is intended to approximate and/or ligate soft tissues, including the use of allograft tissue for orthopaedic surgeries.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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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## 510(k) Summary

### **I. SUBMITTER**

Stryker Endoscopy  
5900 Optical Ct  
San Jose, CA 95138

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

Date Prepared: March 23, 2015

### **II. DEVICE**

Name of Device: Stryker Suture Tape  
Model Numbers: 3910-900-017, 3910-900-018, 3910-900-019  
Common or Usual Name: Suture, Nonabsorbable, Synthetic, Polyethylene  
Classification Name: Nonabsorbable poly(ethylene terephthalate) surgical suture (21 CFR 878.5000)  
Regulatory Class: II  
Product Code: GAT

### **III. PREDICATE DEVICES**

Primary Predicate:  
Teleflex Force Fiber<sup>®</sup> Polyethylene Nonabsorbable Surgical Suture, K033654  
This predicate has not been subject to a design-related recall.

Secondary Predicate:  
Teleflex Force Fiber<sup>®</sup> Blue Polyethylene Nonabsorbable Surgical Suture, K092533  
This predicate has not been subject to a design-related recall.

Reference Device 1:  
4.5mm X 55 mm Parallel Portal Cannula, Class I Exempt Device  
This predicate has not been subject to a design-related recall.

Reference Device 2:  
Stryker ICONIX All-Suture Anchors, K133671  
This predicate has not been subject to a design-related recall.

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

Stryker Suture Tape (herein referred to as the proposed device(s)) is a non-absorbable suture composed 100% of ultra high molecular weight polyethylene (UHMWPE). These devices are braided to be flat in shape and offered in white/blue coloration patterns. Stryker Suture Tape complies with USP standards for #2 suture with the exception of size classifications. Each Suture Tape variation will be cut to length and provided to the end user in a single-use sterile barrier system (SBS).

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

Stryker Suture Tape is intended to approximate and/or ligate soft tissues, including the use of allograft tissue for orthopaedic surgeries.

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

The technological characteristics of Stryker Suture Tape are equivalent to the predicate devices. Both the proposed and the predicate devices feature a braided multifilament design and are composed of ultra high molecular weight polyethylene (UHMWPE). As such, Stryker Suture Tapes and the predicate devices are classified as Class 1 Sutures per USP standards. The proposed and predicate devices are manufactured in the same location using similar processes. Stryker Suture Tape products undergo wash processes identical to the predicate devices. The proposed and predicate devices have similar intended uses.

Proposed and Predicate Device Differences:

##### *Device Geometry*

The predicate devices are round suture products while the proposed devices are flat in shape. Both the predicate and proposed devices do not adhere to USP size classifications. The Stryker Suture Tape products meet minimum requirements of USP standards for knot pull tensile strength. As such, this dimensional deviation from the predicates does not adversely affect the safety and effectiveness of the proposed product.

##### *Coloration*

The predicate devices are offered in all white and all blue colors. The Stryker Suture Tape products are offered in white/blue coloration patterns created through braiding blue and white strands. The proposed and predicate devices are all composed of 100% UHMWPE. The blue colorant for the proposed and predicate devices is the same.

Stryker Suture Tape is substantially equivalent to the identified predicate devices in regard to intended use, materials of construct, performance attributes, and technological characteristics.

#### **VII. PERFORMANCE DATA**

Non-clinical benchtop testing was performed to verify that Stryker Suture Tapes exceed the minimum requirements of USP standards for knot pull tensile strength of nonabsorbable surgical sutures. 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 Suture Tape is substantially equivalent to the predicate devices and will perform as designed within the intended use.