DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 10, 2016

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

Re: K162310
Trade/Device Name: Xbraid TT Suture Tape
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT,
Dated: August 15, 2016
Received: August 17, 2016

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,

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

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 on last page.

510(k) Number *(if known)*

K162310

Device Name

Xbraid TT Suture Tape

Indications for Use *(Describe)*

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

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.

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510(k) SUMMARY
Xbraid TT Suture Tape

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: August 15, 2016

II. SUBJECT DEVICE

Name of Device:	XBraid TT 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:	2
Product Code:	GAT

III. PREDICATE DEVICE

Predicate:
Stryker Suture Tape, K150584
This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

XBraid TT Suture Tape (herein referred to as the proposed device(s)) is a non-absorbable, sterile suture composed 100% of ultra high molecular weight polyethylene (UHMWPE). These devices are braided to be flat in shape and offered in white/violet coloration patterns. XBraid TT Suture Tape complies with USP standards for #2 suture with the exception of size classifications and needle attachment. Three configurations are being proposed that differ only in coloration pattern and dimensions. Each configuration will be cut to length and provided to the end user in a single-use sterile barrier system (SBS).

V. INTENDED USE

XBraid TT 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 design and generic material of construct of the XBraid TT Suture Tape devices are identical to the predicate device. Both the proposed and the predicate devices feature a braided multifilament design and are composed entirely of ultra high molecular weight polyethylene (UHMWPE). As such, XBraid TT Suture Tapes and the predicate devices are classified as Class I Sutures per USP standards.

Proposed and Predicate Device Differences:

Material Formulation
The singular difference in technological characteristics concerns the material formulation, namely, the colorant used. The predicate device is offered in white/blue coloration patterns, while the XBraid TT Suture Tape products are offered in white/violet patterns. The coloration patterns for the proposed and predicate devices are created by braiding colored and white (non-colored) suture strands. This difference in color is due to the proposed devices containing a different colorant than the predicate device. This difference in colorant has been shown to be biologically safe and functionally acceptable within the intended use of the devices. The intended use of the proposed and predicate devices is identical. The new colorant thus raises no new questions of safety and effectiveness and does not represent a significant change to materials of construct.

XBraid TT Suture Tape is substantially equivalent to the identified predicate device 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 the XBraid TT Suture Tape devices meet or exceed the minimum requirements of USP standards for knot pull tensile strength of size #2 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 XBraid TT Suture Tape is substantially equivalent to the predicate device and will perform as designed within the intended use.