DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 13, 2016

Surgical Specialties Corporation
Ms. Karen Sanchez
Regulatory Affairs Specialist
Corredor Tijuana-Rosarito 2000, #24702-B
Ejido Francisco Villa
Tijuana, B.C., C.P. 22235
Mexico

Re: K160744
Trade/Device Name: LOOK™ PTFE Suture
Regulation Number: 21 CFR 878.5035
Regulation Name: Nonabsorbable Expanded Polytetrafluoroethylene Surgical Suture
Regulatory Class: Class II
Product Code: NBY
Dated: June 22, 2016
Received: June 24, 2016

Dear Ms. Sanchez:

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 below.

510(k) Number *(if known)*

K160744

Device Name
LOOK™ PTFE Suture

Indications for Use *(Describe)*
PTFE (polytetrafluoroethylene) suture is indicated for use in all types of soft tissue approximation and/or ligation, including dental and general 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)

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.

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Section 5 - 510(k) Summary

Date Prepared:	June 30, 2016
Company:	Surgical Specialties Corporation Corredor Tijuana-Rosarito 2000 #24702-B, Ejido Francisco Villa Tijuana, B.C., C.P. 22235, Mexico
Contact:	Karen Sanchez Regulatory Affairs Specialist Phone: 484-557-4996 Fax: 610-404-3905 Email: ksanchez@surgicalspecialties.com
Device trade name:	LOOK™ PTFE Suture
Device Common Name:	PTFE Nonabsorbable Surgical Sutures
Device classification:	Non-absorbable expanded polytetrafluoroethylene surgical suture Product Code, NBY 21 CFR 878.5035 Class II
Legally marketed devices to which the device is substantially equivalent:	K072076 Cytoplast PTFE Suture K140415 MonoTex PTFE Suture
Description of the device:	The LOOK™ PTFE Suture is a monofilament, synthetic, non-absorbable, sterile surgical suture composed of high-density polytetraflouroethylene (PTFE). PTFE Suture is provided undyed (White).
Indications for Use:	The LOOK™ PTFE Suture is indicated for use in all types of soft tissue approximation and/or ligation, including dental and general surgeries.

Substantial Equivalence:

The LOOK™ PTFE Suture is substantially equivalent to the predicates Cytoplast PTFE suture and MonoTex PTFE Suture in which the basic features and intended uses are the same. Any differences between the LOOK™ PTFE Suture and the predicates are considered minor and do not raise questions concerning safety and effectiveness.

	LOOK™ PTFE Braided Suture	Cytoplast PTFE Suture (K072076)	MonoTex PTFE Suture (K140415)
Product Code	NBY	Identical	Identical
Suture Characteristic	Non-absorbable expanded polytetrafluoroethylene surgical suture	Identical	Identical
Intended Use	Approximation or ligation of soft tissues	Identical	Identical
Technological Characteristic	Monofilament, uncoated, synthetic nonabsorbable surgical sutures	Identical	Identical
Material	High-density polytetraflouroethylene (PTFE)	Identical	Identical
Sizes	2-0, 3-0, 4-0, 5-0, 6-0 in 18” lengths	2-0, 3-0, 4-0 in 18” lengths	Identical to proposed device
Sterilization	EO	Identical	Identical
Packaging	Device wound onto inner support card, within a Tyvek/Poly Primary Pouch; inside a Tyvek / Poly secondary pouch	Device wound onto inner support card, within a Tyvek / Poly pouch	Device packaged in racetrack design

Performance tests: Non-clinical laboratory performance testing was conducted to confirm that the LOOK™ PTFE Suture conforms to the USP monograph for nonabsorbable sutures for tensile strength and needle attachment. This testing was also conducted to show that the candidate device is substantially equivalent to the predicate devices. This testing was performed in accordance with FDA's Class II Special Controls Guidance Document: Surgical Sutures, Issued June 3, 2003.

Testing was conducted on the LOOK™ PTFE Suture to establish the device expiration date of five years. This testing was performed on both accelerated and real-time aged products. Accelerated aging was performed in accordance with ASTM F1980. The testing of the candidate device was conducted to confirm that the LOOK™ PTFE Suture conforms to the USP monograph for nonabsorbable sutures for tensile strength and needle attachment for the entire shelf life of the product.

Testing performed on the LOOK™ PTFE Suture included the following:

- Diameter per USP <861>
- Needle Attachment per USP <871>;
- Tensile Strength per USP <881>;

All of the acceptance criteria were met at all testing intervals.

Biocompatibility Testing Biocompatibility testing for the LOOK™ PTFE Suture was conducted in accordance with the International Standard ISO 10993-1:2009 "Biological Evaluation of Medical devices- Part 1: Evaluation and testing within a risk management process". A Biological Risk Assessment was conducted for the testing recommended per ISO 10993-1:2009. As a function of the risk assessment, a subset of biocompatibility testing was performed to ensure compliance of the candidate device.
Per ISO 10993-1:2009, the LOOK™ PTFE Suture is classified as an implant, permanent contact (>30 days) with tissue/bone.

Assessments of the candidate device included the following:

- Biological Risk Assessment
- Cytotoxicity Study Using the ISO Elution Method
- ISO Intracutaneous Study in Rabbits
- ISO Guinea Pig Maximization Sensitization Test
- Endotoxin Test
- Material-mediated Rabbit Pyrogen Test

All of the acceptance criteria were met.

Summary The results of the testing demonstrate that the LOOK™ PTFE Suture is substantially equivalent in safety and performance to the predicate devices.