October 06, 2023

Standard Bariatrics, Inc.
Trevor Barton
Project Manager & Staff Product Development Engineer
4300 Glendale Milford Road
Cincinnati, Ohio 45242

Re: K231603
Trade/Device Name: Standard Staple-Line Reinforcement (SSLR23)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OXC
Dated: September 5, 2023
Received: September 5, 2023

Dear Trevor Barton:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2023.10.06 10:09:02 -04'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231603

Device Name

Standard Staple-Line Reinforcement (SSLR23)

Indications for Use *(Describe)*

Standard Staple-Line Reinforcement is indicated for use in bariatric procedures in which gastric tissue transection and resection with staple line reinforcement is needed.

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.

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510(k) Summary

510(k) Number: K231603

Date Prepared: 06-October-2023

I. Submitter's Information

Company Name	Standard Bariatrics, Inc.
Address	4300 Glendale Milford Road Cincinnati, OH 45242 USA
Company Phone Number	+1-513-620-7751
Primary Contact	Trevor Barton Project Manager & Staff Product Development Engineer
Phone Number	859-962-7619
Email address	trevor.barton@teleflex.com

II. Subject Device Information

Device Trade Name	Standard Staple-Line Reinforcement (SSLR23)
Regulatory Class	Class II
Regulation Number	21 CFR 878.3300
Regulation Name	Surgical Mesh
Product Code	OXC - Mesh, Surgical, Absorbable, Staple Line Reinforcement

III. Predicate Device Information

Device Trade Name	GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement
Regulatory Class	Class II
Regulation Number	21 CFR 878.3300
Regulation Name	Surgical Mesh
Product Code	OXC - Mesh, Surgical, Absorbable, Staple Line Reinforcement
FDA clearance	K181940

IV. Device Description

The Standard Staple-Line Reinforcement (SSLR23) is an implantable device designed to be used with Standard Bariatrics' TITAN SGS23R device (K210278) during laparoscopic surgery to position, clamp, staple, and resect long planes of soft flat tissue and organs, such as the stomach. The SSLR23 device consists of 2

(two) sheets of GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material, configured to be used only with TITAN SGS23R and which provides a continuous sheet of Staple-Line Reinforcement for the entire length of the staple-line, up to 23cm in length. The device contains an applicator to aid in the installation of the SSLR23 on the TITAN SGS23R jaws.

The SSLR23 device is single-use and supplied sterile.

V. Indications for Use / Intended Use

INTENDED USE

Intended for staple-line reinforcement of gastric tissue when used with the TITAN Standard Gastric Stapler (SGS23R) during sleeve gastrectomy pouch creation.

INDICATIONS FOR USE

Staple-Line Reinforcement is indicated for use in bariatric procedures in which gastric tissue transection and resection with staple line reinforcement is needed.

VI. Comparison of Technological Characteristics with the Predicate Device

The technological characteristics and specifications of Standard Staple-Line Reinforcement (SSLR23) and the predicate device were evaluated to determine substantial equivalence. Upon reviewing and comparing the intended use, materials, design, principles of operations and overall technological characteristics, Standard Bariatrics determined that the subject device is substantially equivalent to the existing legally marketed device. A summary of the evaluation of substantial equivalence is provided below.

	Subject Device	Predicate Device	Equivalence
Product Name	Standard Staple-Line Reinforcement (SSLR23)	GORE SEAMGUARD Bioabsorbable Staple Line Reinforcement	N/A
Manufacturer	Standard Bariatrics, Inc.	W.L. Gore & Associates, Inc.	N/A
510k information	K231603	K181940	N/A
Device Classification	II	II	Same
Classification Name	Surgical Mesh	Surgical Mesh	Same
Regulation and code	878.3300 OXC	878.3300 OXC	Same
Indications for Use	Standard Staple-Line Reinforcement is indicated for use in bariatric procedures in which gastric tissue transection and resection with staple line reinforcement is needed.	GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement is indicated for use in surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed. It can be used for reinforcement of staple lines during hysterectomy, lung resection, liver resection, bladder reconstruction, bronchial, bariatric, colon, colorectal, esophagus, gastric, mesentery, pancreas, small bowel, and spleen	Equivalent. The indications of the subject device are limited to the TITAN SGS23R procedural indications.

		procedures. It is also intended to be used for reinforcement of suture lines and staple lines (i.e., occlusion of the left atrial appendage during open chest procedures) during cardiac surgery.	
Principle of Operation	Staple line reinforcement in surgical procedures using TITAN SGS23R.	The GORE SEAMGUARD Bioabsorbable Staple Line Reinforcement Material is to be used with surgical stapling devices.	Equivalent. Differences to accommodate different stapler compatibility exist, but the fundamental mode of operation (staple line reinforcement in surgical procedures) is the same.
Single use	Yes	Yes	Same
Material	GORE SEAMGUARD Bioabsorbable Staple Line Reinforcement Material (Synthetic bioabsorbable poly (glycolide: trimethylene carbonate) copolymer (PGA:TMC))	GORE SEAMGUARD Bioabsorbable Staple Line Reinforcement Material (Synthetic bioabsorbable poly (glycolide: trimethylene carbonate) copolymer (PGA:TMC))	Same
MR Compatibility	MR Safe	MR Safe	Same
Stapler Compatibility	The subject device is comprised of the GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material configured to fit Standard Bariatrics' Titan SGS23R Stapler (K210278). Subject and predicate devices possess equivalent fundamental technology. TITAN Standard Gastric Stapler (SGS23R) (K210278)	GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material Configured for Endoscopic Surgical Staplers, specifically designed to fit the geometry of Intuitive SureForm 60™ (K173721). Intuitive SureForm 60™ (K173721)	Equivalent. Differences in configuration for stapler compatibility are expected.
Sterilization	Gamma Irradiation	Gamma Irradiation	Same
Packaging	Supplied in sterile, poly-foil film pouches, with an applicator to facilitate the placement of the device onto the jaws of the TITAN SGS surgical stapler. Desiccant packs are included to preserve device integrity.	Supplied in sterile foil film laminate pouches, with Tyvek® inserts to facilitate placement of the reinforcement material onto the stapler jaws. Desiccant paper/pack are included to preserve device integrity.	Equivalent. Differences in packaging between the subject and predicate devices exist due to device size differences for stapler compatibility.

VII. Summary of Performance Testing

Pre-determined performance specifications were evaluated, tested and verification/validation activities were completed to demonstrate that the subject device, Standard Staple-Line Reinforcement designed to use with Standard Bariatrics' TITAN SGS23R Standard Gastric Stapler (K210278) met the defined criteria. Testing on the subject device included reliability, staple-form, burst pressure, hemostasis, as well as

applicable biocompatibility per applicable parts of ISO 10993-1, *Biological evaluation of medical devices.* Sterilization and packaging validation activities were also completed to support this submission.

Test results provided in this submission demonstrated that the technological differences between the subject and predicate devices are acceptable and do not raise any new type of questions; furthermore, the performance data provides reasonable assurance of safety and effectiveness of the device when used as intended.

No clinical studies were required to support this 510(k) submission.

VIII. Conclusion

The subject device, Standard Staple-Line Reinforcement (SSLR23), shares the intended use and equivalent indications for use as its predicate device. It is concluded that the different technological characteristics do not raise new types of questions and performance data has provided reasonable assurance to demonstrate substantial equivalence and that the subject device can perform as intended.