April 28, 2021

Standard Bariatrics
Alison Sathe
Regulatory Affairs
4362 Glendale Milford Rd.
Cincinnati, Ohio 45242

Re: K210278
Trade/Device Name: Titan SGS
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: January 28, 2021
Received: February 1, 2021

Dear Ms. Sathe:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210278

Device Name
Titan SGS

Indications for Use *(Describe)*
The Titan SGS linear cutter is intended for longitudinal transection and resection of gastric tissue for sleeve gastrectomy pouch creation.

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

I. Submitter's Information

Company Name:	Standard Bariatrics, Inc.
Address:	4362 Glendale Milford Road Cincinnati, OH 45242
Phone Number:	513-658-0328
Fax Number:	513-436-0201
Contact Person:	Alison Sathe
Phone Number:	513-304-7971
Email Address:	alison@regulatorymark.com

Date Prepared: January 28, 2021

II. Device Information

Device Name:	Titan SGS
Common Name:	Staple, Implantable
Regulatory Class:	Class II
Regulation:	21 CFR 878.4750
Product Code:	GDW

III. Predicate Device:

Echelon Flex Power Plus, K140560, 21CFR 878.4750, Class II, Product Code GDW
Ethicon Endo-Surgery, LLC

IV. Device Description

The Titan SGS with implantable staples (Titan Stapler) is a single patient use, sterile instrument used for cutting and stapling gastric tissue for sleeve gastrectomy pouch creation. The Titan Stapler is supplied preloaded with staples, fires once and cannot be reloaded.

The Titan Stapler is comprised of three main sections:

- **Stapler:** located in the sterile field, it has three main sections
  - the handle, which does not contact the patient and is handled by user within the sterile field,
  - the device shaft and end effector which are surgically invasive components,
  - the staples, which are housed in the end effector until they are applied to the tissue where they are permanently implanted.
- **Cable:** permanently attached to the stapler, it is passed from the sterile field to the nonsterile area to connect with the reusable Power Supply Unit, and

- **Power Supply Unit:** which is stored and used in the nonsterile area of the O.R. and powers the stapler opening, closure, and firing

The stapler end effector is 230 mm long and contains 342 staples that are organized in 6 staggered rows, 3 on each side of the cut line. The staples range in closed staple height from 2.2 mm to 1.2 mm. Staples are formed into a traditional 'B' shape; similar to existing devices. As with other powered staplers, the Titan Stapler opens and closes through a simple mechanical linkage housed in the shaft and end effector of the device.

The device of the single-use Titan Stapler and a reusable power source which is supplied separately. There are no accessories supplied with the instrument. The Titan Stapler Power Source is designed to supply energy to the Titan Stapler and has a unique receptable port specific to the Titan Stapler.

V. Intended Use

Intended for transection and resection of gastric tissue.

VI. Indications for Use

The Titan SGS linear cutter is intended for longitudinal transection and resection of gastric tissue for sleeve gastrectomy pouch creation.

VII. Technological Characteristics

The technological specifications of Titan Stapler and its predicate have been evaluated to determine equivalence. As detailed on Section 012 – *Substantial equivalence* of this 510(k) submission, upon reviewing and comparing intended use, design, materials, principle of operation and overall technological characteristics, the Titan Stapler is determined by Standard Bariatrics to be substantially equivalent to existing legally marketed devices (Table 1).

Table 1: Overview of Substantial Equivalence

	Standard Bariatrics' Device	Predicate Device	Determination
Product Name	Titan SGS	Echelon Flex Powered Plus	N/A
510(k) Holder	Standard Bariatrics	Ethicon Endo-Surgery, LLC	N/A
Regulatory Information			
510(k) Number	TBD	K140560	N/A
Product Code	GDW	GDW	Same
Regulation	21 CFR 878.4750 Implantable Staple	21 CFR 878.4750 Implantable Staple	Same
Classification	II	II	Same
Design Information			
Principle of operation	Tissue is placed between jaws of stapler, jaws are closed, stapler is fired by depressing trigger, knife transects tissue as staples are formed in tissue	Tissue is placed between jaws of stapler, jaws are closed, stapler is fired by depressing trigger, knife transects tissue as staples are formed in tissue	Same

Method of Insertion	Used in laparoscopic applications by insertion through a trocar	Used in laparoscopic applications by insertion through a trocar	Same
Power Source	DC powered - wall outlet	DC powered - battery	Equivalent
Staple Shape	B	B	Same
Staple Material	Titanium	Titanium Alloy	Equivalent.
Closed Staple Height	1.2 – 2.2	1.0-2.3mm	Equivalent
Staple Arrangement	3 staggered rows on each side of cut line	3 staggered rows on each side of cut line	Same
Staple Line Extension Past Cut Line	1.5 staples (6.0 mm)	1.5 staples (6.0 mm)	Same
Method of Resection	Blade	Blade	Same
Method of Activation	Trigger to open/close device jaws and fire	Trigger to open/close device jaws and fire	Same
Sterilization	Provided sterile via gamma. 10^{-6} SAL	Provided sterile via gamma. 10^{-6} SAL	Same

The technological differences between the predicate and subject device do not impact the safety and effectiveness of the subject device as described in Section 012 – *Substantial Equivalence.*

VIII. Performance Data

Non-Clinical

Performance Testing to evaluate and compare the technological and performance characteristics included bench, animal, and clinical studies.

Pre-determined performance specifications were tested, and verification and validation activities were conducted to demonstrate that the Titan Stapler met the defined criteria. Testing on the subject device included biocompatibility, MR compatibility, usability, Electrical Safety and EMC testing. Animal studies evaluating hemostasis as compared to the predicate device and a survival study were conducted.

Performance evaluation of the Titan Stapler during the design validation and verification was completed by applying methods of internationally recognized standards such as, EN ISO 10993-1:2018 *Biological evaluation of medical devices – Part 1: Evaluation and Testing within a risk management process,* EN ISO 14971:2012, *Medical Devices – Application of Risk Management to Medical Devices*, IEC 60601-1:2005/(R)2012, *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*, ISO 11737-2:2009, Sterilization of Medical Devices – Microbiological Methods – Part 2: *Tests of sterility performed in the definition, validation and maintenance of a sterilization process*, among others.

The Titan Stapler met acceptance criteria and demonstrated comparable performance to the predicate device for the equivalent indications for use.

Clinical

A comparative clinical study including 36 subjects at one site was conducted between the Titan Stapler and the predicate device, the Echelon Flex Powered Plus GST System on excised human stomach. Results demonstrated substantially equivalent performance between the two devices for the equivalent indications for use.

IDE G200085 with protocol title *Multisite Study of Titan SGS Stapler in Longitudinal Gastric Resection* was developed based on FDA's recommendations (Q200176). The study enrolled 62 subjects at three sites. Results demonstrated that the Titan SGS does not raise any new types of questions and the performance data provided reasonable assurance of safety and effectiveness to demonstrate substantial equivalence.

IX. Conclusion

The Titan Stapler has the same intended use as the Echelon Flex Powered Plus GST System. The conclusion drawn from the nonclinical and clinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device. The design/technological differences do not raise any new types of questions and the performance data provided reasonable assurance of safety and effectiveness to demonstrate substantial equivalence.