April 9, 2020

Standard Bariatrics
Ms. Alison Sathe
Vice President, Regulatory
4362 Glendale Milford Rd.
Cincinnati, Ohio 45242

Re: K200517
Trade/Device Name: Standard Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: February 28, 2020
Received: March 2, 2020

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200517

Device Name
Standard Trocar

Indications for Use *(Describe)*
The Standard Trocar is a sterile, single-use device consisting of an obturator, a cannula, a 5mm adapter and introducer sheath. This system is indicated for use in general and abdominal minimally invasive surgical procedures to establish a path of entry or to gain access through tissue planes and/or potential spaces for endoscopic instruments.

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, Vice President, Regulatory
Phone Number:	513-304-7971
Email Address:	alison@standardbariatrics.com

Date Prepared:	February 27, 2020

II. Device

Tradename:	Standard Trocar
Common Name:	Trocar
Classification Name:	Endoscope and Accessories
Classification:	Class II (21CFR876.1500)
Product Code:	GCJ

III. Predicate Device

Applied Medical Modular Trocar, K060096, K083638, Class II (21CFR876.1500), Product Code GCJ, Applied Medical Resources Corporation

IV. Device Description

The Standard Trocar is a single-patient-use disposable trocar manufactured from biocompatible medical plastics. The device is comprised of a trocar cannula, obturator, 5 mm adaptor, and introducer sheath. The Standard Trocar is a sterile, single patient use surgical instrument intended to establish a port of entry for 19mm outer diameter instruments to be used during minimally invasive procedures. The 5 mm adaptor provides the means for the trocar to also be used with 5 mm diameter instruments. The trocar is compatible with commercially available laparoscopic instruments. In addition, as Standard Bariatrics develops additional laparoscopic instruments, the Standard Trocar will accommodate those devices. The Standard Trocar is sterilized using gamma irradiation and provided to the user in a Tyvek tray with peel lid.

V. Indications for Use:

The Standard Trocar is a sterile, single-use device consisting of an obturator, a cannula, a 5mm adapter and introducer sheath. This system is indicated for use in general and abdominal minimally invasive surgical procedures to establish a path of entry or to gain access through tissue planes and/or potential spaces for endoscopic instruments.

VI. Intended Use:

The Standard Trocar is intended to be used by a surgeon on a single patient during a single laparoscopic surgery under normal operating conditions. It is intended to create and maintain a port of entry into the body through tissue planes and/or potential spaces for endoscopic instruments.

VII. Technological Characteristics

The Standard Trocar and its predicate have been evaluated to determine substantial equivalence technological characteristics are provided in Table 1.

Table 1: Overview of technological characteristics

	Standard Trocar	Predicate Device
Product Name	Standard Trocar	Modular Trocar System
510(k) Holder	Standard Bariatrics	Applied Medical
510(k) Number	TBD	K060096, K083638
Product Code	GCJ	GCJ
Regulation	21 CFR 876.1500 Laparoscope, General & Plastic Surgery	21 CFR 876.1500 Laparoscope, General & Plastic Surgery
Classification	II	II
Intended Use	To be used by a surgeon on a single patient during a single laparoscopic surgery under normal operating conditions. It is intended to create and maintain a port of entry into the body through tissue planes and/or potential spaces for endoscopic instruments.	To be used by a surgeon on a single patient during a single laparoscopic surgery under normal operating conditions. It is intended to create and maintain a port of entry into the body through tissue planes and/or potential spaces for endoscopic instruments.
Indications for Use	The Standard Trocar is a sterile, single-use device consisting of an obturator, a cannula, a 5mm adapter and introducer sheath. This system is indicated for use in general and abdominal minimally invasive surgical procedures to establish a path of entry or to gain access through tissue planes and/or potential spaces for endoscopic instruments.	Applied Medical Modular Trocar Systems are sterile, single-use devices consisting of an obturator, a cannula and seal. These systems are indicated for use in general, abdominal, gynecological and thoracic minimally invasive surgical procedures to establish a path of entry or to gain access through tissue planes and/or potential spaces for endoscopic instruments.
How Supplied	Single use, sterile	Single use, sterile
Principle of operation	Obturator is inserted into canula, minor skin incision is made, device is advanced through incision to access desired anatomical space. Laparoscopic instruments are passed through the device. Upon completion, device is removed and port is closed utilizing traditional closure methods.	Obturator is inserted into canula, minor skin incision is made, device is advanced through incision to access desired anatomical space. Laparoscopic instruments are passed through the device. Upon completion, device is removed and port is closed utilizing traditional closure methods.
Components	Obturator, cannula	Obturator, cannula
Optional Accessory	5 mm adaptor Introducer sheath	None

	Standard Trocar	Predicate Device
Length[1]	100 mm	100 mm
Shaft Outer Diameter[3]	23 mm	19 mm
Shaft Inner Diameter[3]	20 mm	16 mm
Valve	Quad valve	Quad valve
Seal Shape	Lip seal	Multi-leaflet seal
Method of affixing	Suture loops and ridges/ threads on shaft	Suture loops and ridges/ threads on shaft
Tip shape	Bladeless conical tip	Bladeless conical tip
Optical Channel	No	Yes
Insufflation Port	No	Yes
Shelf Life	1 year	2 years
Biocompatibility	Biocompatible per ISO 10993-1	Biocompatible per ISO 10993-1
Sterilization	Provided sterile via gamma	Provided sterile via gamma
SAL	10^{-6} SAL	10^{-6} SAL

VIII. Performance Testing

Performance Testing was conducted to evaluate and compare the technological and performance characteristics. Pre-determined performance specifications were tested and verification and validation activities were conducted to demonstrate that the Standard Trocar met the defined criteria. Testing on the subject device included biocompatibility, mechanical testing, and usability.

Performance evaluation of the Standard Trocar 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*, and 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 Standard Trocar met acceptance criteria and demonstrated comparable performance to the predicate device for the equivalent indications for use.

IX. Conclusions

The results from the nonclinical testing demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device. The design/technological differences do not raise any new types of questions and the performance data provide reasonable assurance of safety and effectiveness to demonstrate substantial equivalence. The subject and predicate devices are therefore substantially equivalent.

[1] Per the 510(k) summary, the device is available in lengths ranging from 50-150mm. The device Standard Bariatrics obtained for comparison is the model AM15 which is reflected in this table.