ARTMENT 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 17, 2016

Gordian Surgical Ltd.
℅ Dr. Susan Alpert
Regulatory Consultant and U.S. Agent
200 Park Avenue, Unit 111
Minneapolis, Minnesota 55415

Re: K160564
Trade/Device Name: TroClose1200™ Trocar System
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM, GCJ
Dated: October 10, 2016
Received: October 17, 2016

Dear Dr. Alpert:

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,

Jennifer R. Stevenson -A

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)*
K160564

Device Name
TroClose1200™

Indications for Use *(Describe)*
The TroClose1200™ bladeless trocar is intended for use in a variety of gynecologic, general and urologic endoscopic procedures to create and maintain a port of entry and to facilitate the delivery of absorbable sutures and anchors through soft tissues of the body during endoscopic/ laparoscopic surgery.
The trocar may be used with or without visualization for primary and secondary insertions.

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**

(As required by 21 C.F.R. § 807.92)

**TroClose1200™**

**Company:**

GORDIAN SURGICAL Ltd.
Misgav Industrial Park
P.O.Box 499
Karmiel
2161401, ISRAEL.
Fax: + 972 72 260 7200

**Contact Person:**

Dr. Susan Alpert, M.D.
Mobile: 612 202 7019
E-MAIL: drsusanalpert@gmail.com

**Date Prepared:** October 10, 2016

**Trade Name:** TroClose1200™
**Common Name:** Trocar with Closure Device
**Classification Name:** Absorbable poly(glycolide/l-lactide) surgical suture
**Regulation Number:** 21 CFR §878.4493
**Product Code:** GAM (absorbable PGLA suture) , GCJ (Endoscope and accessories)

**Predicate Devices**

Primary Predicate Device- Closure Device- neoClose® (**K123280**) (21 CFR §876.1500, product code GCJ)

Secondary Predicate Device- Trocar- Versaport™ V2 Bladeless Trocar (**K130435**) (21 CFR §876.1500, product code GCJ).

**Intended Use / Indications for Use**

The TroClose1200™ bladeless trocar is intended for use in a variety of gynecologic, general and urologic endoscopic procedures to create and maintain a port of entry and to facilitate the delivery of absorbable sutures and anchors through soft tissues of the body during endoscopic/ laparoscopic surgery. The trocar may be used with or without visualization for primary and secondary insertions.

**Device Description**

The TroClose1200™ is a Trocar system comprised of an Obturator and a Cannula including pre-loaded sutures. It includes a bladeless Obturator, designed to allow penetration and positioning at the required site within the abdomen, and several single use Cannulas, which serve as working channels for the procedure. The Cannulas are pre-loaded with two absorbable PGLA sutures, each attached to an absorbable PLGA anchor. The deployment of the anchors and sutures ("closure device) is achieved by utilizing two pushers within the Obturator as a deployment mechanism.

The TroClose1200™, as one unit, consists of the following components:

- *An Obturator,* which is the part of a trocar that allows the insertion of the trocar (after routine scalpel-made incision). An *Obturator* is for single patient use. For this purpose, the Company's *Obturator* is bladeless, similar to the predicate *Obturator*. In addition, the Company's *Obturator* has a set of 2 pushers that deploy (the closure device's deployment mechanism) the anchors with sutures attached from the Cannula for later closure.

- *A Cannula,* which is the part of a trocar that establishes the working channel through which the surgeon introduces surgical tools while keeping the $CO_2$ in the abdominal lumen. The *Cannula* is for single use and is similar to the predicate trocar *Cannula*. In addition, the Company's Cannula has 2 absorbable anchors attached to absorbable threads, at $180^0$ to each other, as the closure device, which is similar to the predicate closure device. The thread (suture) is made of absorbable PGLA and the anchors are made of absorbable PLGA and is designed to close the access port by suturing the abdominal wall's fascia.

GORDIAN 's TroClose1200™ is manufactured from routinely used medical device biocompatible materials.

Like its' predicates, this disposable device is provided sterile (by EtO) and intended for single patient (Obturator) and single use (Cannula) only.

**Technological Characteristics/ Principals of Operation**

Gordian's Single Patient Use / Single Use TroClose1200™ has similar technological characteristics, and use the same principles of operation as the predicates. The only technological differences between the TroClose1200™ and its predicates are: (1) the Trocar predicate has a marketing feature for optics (2) the trocar predicate has a greater variety of sizes, (3) the closure device predicate's anchor is narrower and longer than the TroClose1200™ anchor and has a slightly different configuration design (4) the deployment timing of the anchors in the TroClose1200™ is at the beginning of the laparoscopic procedure as the TroClose1200™ has both the closure device and trocar in the same device while the predicate closure device deployment is at the end of the procedure, (5) the TroClose1200™ operation has two additional

steps consisting of pulling and pushing an applicator for coking and deployment of the anchors and sutures, (6) the trocar predicate device has an additional indication of “thoracic”, and (7) the TroClose1200™ uses more common PGLA sutures presenting knot-pull tensile strength with a minimum and average of 38.2N, while the neoClose® uses PGA sutures presenting knot-pull tensile strength with a minimum and average of 26.3N.

**Performance Data**

As for the predicate devices, both under 21 CFR 876.1500 and product code GCJ, no applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for the device and similar devices regulated under this regulatory number and product code.

For the TroClose1200™ regulation and product code (21 CFR878.4493 and product code GAM) performance tests were done also according to SUTURE and included mechanical tests and degradation testing according to ASTM F1635-11, knot-pull tensile strength (per absorbable sutures USP monograph instructions), needle attachment strength (per absorbable sutures USP monograph instructions), biocompatibility testing according to ISO 10993, sterilization according to ISO 11135, and a GLP animal studies. These tests demonstrated that the TroClose1200™ is substantially equivalent to its predicates, by successfully achieving its intended use, which is the same as the predicates.

The following table summarizes the non-clinical testing performed for the TroClose1200™.

| No. | Category | Name of test |
|---|---|---|
| 1. | Sterilization & Shelf life including packaging, functionality and moisture level testing | Shelf life testing (packaging sealing after shelf life) |
| 2. | | Sterilization validation including EtO residues (per ISO 11135) |
| 3. | | Packaging validation at time “0” (Per ISO 11607) |
| 4. | | Functionality Test |
| 5. | Bench study | o Mechanical testing<br>o Obturator and Cannula detachment force<br>o Instrument Drag Forces into and from the Cannula<br>o Device marking durability<br>o Micro-laser welding Process Qualification<br>o Trocar Seal System Durability, demonstrated by Air Leak Performance |
| 6. | Tests per USP for absorbable sutures | o Knot pull tensile strength (test method as described in USP<881>)<br>o Needle attachment tensile strength (per USP<871> with the test method described in USP<881>) )<br>o Diameter (test method as described in USP<861>)<br>o Length (USP absorbable suture monograph)<br>o Degradation (per ASTM F1635-11) |

| No. | Category | Name of test |
|---|---|---|
| 7. | Anchors Strength | o Degradation profile (per ASTM F1635-11)<br>o Creep test<br>o Cyclic test |
| 8. | Biocompatibility (per ISO 10993 and Blue Book Memorandum #G95-1) for the entire final product including sutures and anchors unless otherwise indicated | o Cytotoxicity (performed by NAMSA)<br>o Irritation (performed by NAMSA)<br>o Sensitization (performed by NAMSA)<br>o Acute systemic toxicity (performed by NAMSA)<br>o Pyrogenicity (performed by NAMSA)<br>o Sub-chronic toxicity **for sutures and anchors** (via rationale allowed by ISO 10993-1 and FDA Draft guidance "Use of International Standard ISO -10993-1 "Biological Evaluation of Medical Devices Part 1- Evaluation and testing" issued on 23 Apr 2013).<br>o Genotoxicity **for anchors** (via rationale allowed by ISO 10993-1 and FDA Draft guidance "Use of International Standard ISO -10993-1 "Biological Evaluation of Medical Devices Part 1- Evaluation and testing" issued on 23 Apr 2013) and as test performed by NAMSA (by the suture manufacturer) **for the sutures**.<br>o Implantation **for anchors** (via rationale allowed by ISO 10993-1 and FDA Draft guidance "Use of International Standard ISO -10993-1 "Biological Evaluation of Medical Devices Part 1- Evaluation and testing" issued on 23 Apr 2013) and as test performed by NAMSA (by the suture manufacturer) **for the sutures**.<br>o Chronic toxicity **for sutures and anchors** (via rationale allowed by ISO 10993-1 and FDA Draft guidance "Use of International Standard ISO -10993-1 "Biological Evaluation of Medical Devices Part 1- Evaluation and testing" issued on 23 Apr 2013).<br>o Carcinogenicity **for sutures and anchors** (via rationale allowed by ISO 10993-1 and FDA Draft guidance "Use of International Standard ISO -10993-1 "Biological Evaluation of Medical Devices Part 1- Evaluation and testing" issued on 23 Apr 2013).<br>o In-vitro Hemolysis Study **for the sutures** as test performed by NAMSA (by the suture manufacturer). |

| No. | Category | Name of test |
|---|---|---|
| 9. | GLP Acute and sub-chronic animal studies | o Acute GLP animal study testing TroClose1200™, neoClose®, Versaport™ V2 trocar and hand suturing.<br>o Sub-Chronic GLP animal study testing TroClose1200™ closure device vs. neoClose® closure devices used with Versaport™ V2 trocar. |
| 10. | Usability testing | o Perform procedure after reading the IFU<br>o Device functionality<br>o Device ease of use |

Performance testing demonstrated that the functionality of the combined device to act as trocar and closure device is comparable to the use of the two functions provided by separate devices.

**Substantial Equivalence**

Gordian's TroClose1200™ has the same intended use with minor modifications (excluding thoracic use) and similar technological characteristics as its predicate devices. Both the TroClose1200™ and the predicate Obturators are bladeless and provide an airtight cannula as a working channel. They are made of similar commonly used materials. Both the TroClose1200™ and predicate closure devices use anchors with sutures, and are made from similar bioabsorbable materials.

The TroClose1200™ principles of operation are the same as other trocars for the trocar function, and the same principle of operation as other cleared devices for the closure device function. The trocar has similar sizes and dimensions as other trocars, and uses the same approach to establish the port of entry. The closure device uses the same principle of operation as the predicate device, deploying anchors with attached sutures into the port of entry, on both sides of the cannula.

Performance testing confirms that the minor differences in technological features compared to the predicates do not adversely impact performance. Thus, the TroClose1200™ is substantially equivalence to the predicates.

These minor differences do not present any new issues of safety or effectiveness as confirmed by the company's bench testing and the GLP acute and sub-chronic animal testing and usability testing. Thus, the TroClose1200™ is substantially equivalent to neoClose closure device by NeoSurgical Ltd., **K123280** and to the Versaport™ V2 Bladeless Trocar by Covidien, **K130435**.