December 16, 2025

Gordian Surgical, Ltd.
% Matthieu Kirkland
Head of Quality & Regulatory Affairs
Avio Medtech Consulting
2300 Myrtle Ave.
Suite 200
St Paul, Minnesota 55114

Re: K253620
Trade/Device Name: TroClose 1200
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM, GCJ
Dated: November 13, 2025
Received: November 18, 2025

Dear Matthieu Kirkland:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery Devices
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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.

510(k) Number *(if known)*
K253620

Device Name
TroClose 1200

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

K253620

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Date Prepared: October 30, 2025

Trade Name: TroClose1200™ Trocar System
Common Name: Trocar with Closure Device
Classification Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture.
Regulation Number: 21 CFR §878.4493
Product Code: GAM, GCJ

Predicate Devices

Trade Name: TroClose1200™ Trocar System (K171494, K160564)
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Product Code: GAM, GCJ

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 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 CO2 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 sutures, at 180º to each other, as the closure device, which is similar to the predicate closure device. The suture (thread) is made of absorbable PLGA and the anchors are made of absorbable PLGA and are 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 device is provided sterile (by EtO) and intended for single patient (Obturator) and single use (Cannula) only.

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.

Summary of Technological Characteristics

	Modified TroClose1200™	TroClose1200™ (K171494 and K160564)	Conclusion / Justification
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.	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.	Identical
Patient Population	Not for use with patients under the age of 13 years or under 45kg (99.2lbs/Pounds)	Not for use with patients under the age of 13 years or under 45kg (99.2lbs/Pounds)	Identical
User Population	• Gynecologic Surgeons • General Surgeons • Urologic Surgeons • Minimally Invasive Surgeons • Laparoscopic Surgeons	• Gynecologic Surgeons • General Surgeons • Urologic Surgeons • Minimally Invasive Surgeons • Laparoscopic Surgeons	Identical
Technological Characteristics	Cannula (enabling access for laparoscopic tools) loaded with the closure device (Anchors + Sutures) deployed by designated pushers embedded as part of the Bladeless Obturator (enabling insertion).	Cannula (enabling access for laparoscopic tools) loaded with the closure device (Anchors + threads) deployed by designated pushers embedded as part of the Bladeless Obturator (enabling insertion).	Identical
Main Components	*Obturator and Cannula*	*Obturator and Cannula*	Similar – several component differences (geometrical / material) yet main assemblies allow for identical principles of operation and performance. Bench testing demonstrates the subject device meets the same performance requirements as the predicate device.

Biocompatibility	Biocompatible materials per applicable standards Component material changes: • Reducer changed from perylene-coated silicon to polyisoprene • Deployment handle changed from IXCF® to Polycarbonate • Pushers changed from 17-4pH alloy to 300 series stainless-steel Obturator changed from IXCF® to Grivory	Biocompatible materials per applicable standards	Same – Testing has been performed to confirm no impact on the biocompatibility of the device based on material changes.
Sterilization	EtO	EtO	Identical
Packaging System	Aluminum Foil	Aluminum Foil	Identical

The Single Patient Use / Single Use Gordian's TroClose1200™ has identical technological characteristics to its predicate device. The Obturator component of the Trocar is bladeless, having an airtight Cannula as a working channel, and is made of similar materials as the Trocar Predicate. The Closure Device component (place within the Cannula) uses identical anchors with identical sutures as the predicate.

The TroClose1200™ principles of operation remain identical, and the identical principles of operation for the closure device function.

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 modifications made to the TroClose1200™, tests included mechanical tests (per absorbable sutures USP monograph instructions), needle attachment strength (per absorbable sutures USP monograph instructions), biocompatibility assessment according to ISO 10993-1, and sterilization validation per ISO 11135. These tests demonstrated that the TroClose1200™ is substantially equivalent to its predicates, by successfully achieving its intended use, which is the identical to the predicate.

No.	Category	Test Name
1.	Sterilization & Shelf life including packaging and functionality	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	- Mechanical testing - Obturator and Cannula detachment force - Instrument Drag Forces into and from the Cannula - Trocar Seal System Durability, demonstrated by Air Leak Performance
6.	Tests per USP for absorbable sutures	- Knot pull tensile strength (test method as described in USP<881>) - Needle attachment tensile strength (per USP<871>) with the test method described in USP<881>) - Diameter (test method as described in USP<861>) - Length (USP absorbable suture monograph)
7.	Biocompatibility (per ISO 10993) for the entire final product including sutures and anchors unless otherwise indicated.	- Cytotoxicity - Irritation - Sensitization - Acute systemic toxicity - Pyrogenicity - Biological Risk Assessment (performed by NAMSA)

For modifications made to the TroClose1200™, biocompatibility and performance testing for the suture were leveraged from previous clearances (K171494, K160564).

The performance testing demonstrated that the functionality of the modified device is substantially equivalent to the predicate device.

Conclusions

Gordian's modified TroClose1200™ has identical intended use and identical technological characteristics as its

predicate device. They are made of similar commonly used (biocompatible) materials. Both TroClose1200™ use anchors with sutures, which remain identical.

The TroClose1200™ principles of operation remain identical.

Performance testing confirms that the minor changes, including manufacturing site, sterilization site and geometrical / design configuration, compared to the predicates do not impact performance. Thus, the TroClose1200™ is substantially equivalence to the predicates.

These differences do not present any new issues of safety or effectiveness as confirmed by the company's bench testing. Thus, the modified TroClose1200™ is substantially equivalent to the previously cleared TroClose1200™ (K171494, K160564).