February 27, 2026

Vigor Medical Technologies , Ltd.
% Bosmat Friedman
Regulatory Consultant
ProMedoss, Inc.
6026 Beech Cove Ln
Charlotte, North Carolina 28269

Re: K252714
Trade/Device Name: C-Lant Port
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: January 25, 2026
Received: January 26, 2026

Dear Bosmat Friedman:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.02.27 12:09:13 -05'00'

Colin Kejing Chen, Ph.D.
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252714

Please provide the device trade name(s).

C-Lant Port

Please provide your Indications for Use below.

The C-Lant Port is intended for use in a variety of endoscopic procedures to provide a port of entry into the abdominal and thoracic cavities.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary [Traditional 510(k)]
C-Lant Port
510(k) Number K252714

1 SUBMITTER

Applicant's Name:

Vigor Medical Technologies, Ltd.
13 Yohanan Hasandlar St.,
Haifa, 3296213
Israel

Company Contact:

Irina Kavounovski
Irina@vigormt.com

Regulatory Contact

Bosmat Friedman
Regulatory Affairs Consultant
6026 Beech Cove Ln.
Charlotte, NC 28269
Phone: 980-308-1636
bosmat.f@promedoss.com

Date Prepared: February 26, 2026

Trade Name:
C-Lant Port

Classification Code:
Device: laparoscope, general & plastic surgery
Product Code: GCJ
Regulation No: 876.1500
Class: 2
Review Panel: General & Plastic Surgery

2 PREDICATE DEVICE

Primary Predicate:

- SoftFix Balloon Trocar, manufactured by Unimax Medical Systems Inc., cleared under K211577; Product Code: GCJ.
- Reactor™ Trocar and Sleeve, manufactured by Sharp Medical Devices, LLC, cleared under K150549; Product Code: GCJ.
- Fixation trocar, manufactured by Applied Medical Resources Corporation, cleared under K083638; Product code: GCJ.

Reference device:

- Port Access System, manufactured by Surgical Innovations Limited, cleared under K210495; Product Code: GCJ.

3 DEVICE DESCRIPTION

The C-Lant Port is a sterile, single-use access system comprised of a trocar and a port with a self-fixating element, designed to provide a secure and sealed port of entry into the thoracic or abdominal cavity during a variety of endoscopic procedures. The device incorporates a retractable blade trocar for controlled penetration, which automatically re-sheaths to reduce the risk of internal injury once the cavity is accessed. Upon withdrawal of the delivery system, an internal fixation element expands into a flower-like configuration that anchors the device against the inner wall, while an external fixation disk with a soft foam interface prevents over-insertion. The integrated iris sealing mechanism rotates to provide a hermetic seal around catheters or tubes up to and including 28Fr, allowing reliable drainage or instrument passage without leakage.

4 INDICATIONS FOR USE

The C-Lant Port is intended for use in a variety of endoscopic procedures to provide a port of entry into the abdominal and thoracic cavities.

5 SUBSTANTIAL EQUIVALENCE

The following table provides a comparison with the predicates:

Feature	**C-Lant Port**	**SoftFix Balloon Trocar (K211577)**	**Fixation trocar (K083638)**	**Reactor™ Trocar and Sleeve (K150549)**
Reg. Number	876.1500	876.1500	876.1500	876.1500
Product Code	GCJ	GCJ	GCJ	GCJ
Indication for Use	The C-Lant Port is intended for use in a variety of endoscopic procedures to provide a port of entry into the abdominal and thoracic cavities.	The SoftFix™ Balloon Trocar have application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments into the body cavity of patients.	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.	The Sharp Medical Reactor Trocar and Sleeve has indications in the creation of a port of entry into the thoracic cavity and allows the user to create and maintain limited access into the chest for the insertion of chest tube placement.
Principle of Operation	The C-Lant Port operates by using a trocar with a retractable blade to create an entry	The SoftFix™ Balloon Trocar operates by inserting a cannula equipped	A bladeless, optical trocar system employing a blunt separator-tip obturator that separates tissue	The Reactor™ Trocar and Sleeve employs an obturator with a

Feature	C-Lant Port	SoftFix Balloon Trocar (K211577)	Fixation trocar (K083638)	Reactor™ Trocar and Sleeve (K150549)
	channel through the body wall, after which the blade automatically re-sheaths to minimize risk of internal injury. Once the delivery system is withdrawn, an internal fixation element expands to anchor the port internally, while an external disk prevents over-insertion. A rotatable iris sealing mechanism then establishes a hermetic seal around instruments, catheters, or tubes (≤28 Fr), ensuring secure positioning and effective drainage or access throughout the procedure	with an inflatable, latex-free balloon and movable bolster through the incision into the body cavity; once in position, the balloon is inflated to anchor and stabilize the port while minimizing fascial trauma, and the movable bolster (ring or cone) further secures cannula placement against migration. A built-in seal and stopcock maintain insufflation pressure and allow unrestricted passage of endoscopic instruments while conserving pneumoperitoneum	along natural fiber lines under direct visualization. Once the peritoneum is traversed, pneumoperitoneum is initiated with minimal penetration (~3 mm), and a sealed cannula remains in place for instrument access.	retractable, circular scalpel-shaped blade that momentarily extends (about 1 mm) when a trigger is squeezed to carve through tissue, then immediately retracts to minimize the risk of internal injury. Once the cavity is accessed, the clear sleeve remains in place—accommodating instruments up to 12 mm or 36 Fr—and integrates a seal to facilitate chest tube placement while maintaining secure access into the thoracic cavity
Anatomical Site	Abdominal and Thoracic cavities	Body cavity (includes Abdominal and Thoracic cavities	Peritoneal cavity (abdominal), with use in thoracic and general minimally invasive procedures	Thoracic cavities
Port Fixation	Achieved by fixation element that is deployed once the delivery device (obturator) is removed	Achieved via ballon inflation prior to removal of obturator.	Achieved via balloon and/or stabilization features (e.g., non-latex balloon, retention disc, Z-thread options) to secure against trocar migration.	N/A – access port removed after chest tube insertion
Cannula Dimensions	Outer Diameter: 14.9 mm	Diameter: 5-12mm	Diameter: 5, 11, and 12 mm	NA

Feature	C-Lant Port	SoftFix Balloon Trocar (K211577)	Fixation trocar (K083638)	Reactor™ Trocar and Sleeve (K150549)
	Length: 64.5 mm	Length:70-100 mm	Length: 75, 100, and 150 mm.	
Device compatibility	Up to and including 28 Fr.	Not specified, likely up to 36 Fr.	Compatible with standard laparoscopic instruments (18–36 Fr) and laparoscopes.	Up to and including 36 Fr.
Biocompatibility	Tested for cytotoxicity, sensitization, irritation, acute systemic toxicity and pyrogenicity per ISO 10993	Tested for cytotoxicity, sensitization, irritation per ISO 10993	Biocompatible per ISO 10993	Biocompatible per ISO 10993
Single use	Yes	Yes	Yes	Yes
Sterility	Gamma	EtO	Gamma	Gamma

The C-Lant Port demonstrates substantial equivalence to its identified predicate devices without introducing new safety and effectiveness concerns.

6 PERFORMANCE DATA

The following performance data is provided in support of our substantial equivalence claim:

Sterilization and Shelf-Life:

The C-Lant Port device is supplied sterile via Gamma irradiation. Sterilization validation was performed in accordance with ISO 11137-1, ISO 11137-2, and ISO 13004:2022. Shelf-life testing was performed to evaluate package integrity and device functionality following accelerated aging and simulated transit conditioning.

Biocompatibility:

The following biocompatibility tests were performed on the C-Lant Port:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity

Non-Clinical Performance Testing:

The C-Lant Port device has undergone and successfully passed the following tests:

- Dimensional Verification
- Trocar Activation & Safety.
- Self-Fixation & Length Adaptation
- Port Access & Iris Functionality

- Bond Integrity
- Penetration Performance
- Smooth Disassembly
- Iris Sealing
- MRI Safety
- Usability Testing
- Penetration Comparison test report
- Gas Leakage Comparison test report
- Visibility Comparison Test report

7 CONCLUSION

The C-Lant Port shares the same intended use, principles of operation, and core technological characteristics with identified legally marketed predicate devices. Where technological differences exist—such as the incorporation of a self-expanding fixation element and iris sealing mechanism—comprehensive bench, performance, and usability testing confirm that these features do not raise new questions of safety or effectiveness. Accordingly, the evidence supports that the C-Lant Port performs as safe and effective as its predicates for the requested indications for use.