July 11, 2025

Sinolinks Medical Innovation, Inc.
Juan Zhao
Director of Compliance & Regulatory Affairs Department
No.10 Ziwei Road, Zhonglou Zone
ChangZhou, Jiangsu CN 213023

RE: K250820
Trade/Device Name: Disposable Trocars
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 11, 2025
Received: June 11, 2025

Dear Juan Zhao:

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,

James H. Jang -S
Digitally signed by James H. Jang -S
Date: 2025.07.11 10:38:53 -04'00'

James Jang, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K250820

Device Name
Disposable Trocars

Indications for Use *(Describe)*
The Disposable Trocars have applications in minimally invasive surgical procedures to establish a path of entry for endoscopic instruments in abdominal area.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**510(k) Summary**

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K250820.

1. **Submitter:**

Sinolinks Medical Innovation, Inc.
No.10 Ziwei Road, Zhonglou Zone, Changzhou 213023 Jiangsu China.
Contact Person: Juan Zhao
Contact Title: Director, Regulatory Affairs
Phone: +86-51988021670
Email: zhaojuan@sinolinks.com.cn

Date Prepared: July 9, 2025

2. **Proposed Device:**

Trade Name: Disposable Trocars
Common Name: Disposable Trocars
Classification Name: Endoscope and accessories
Regulation Number: 876.1500
Product Code: GCJ
Regulation Class: II

3. **Predicate Device(s):**

Primary Predicate Device:
Trade Name: Disposable Bladeless Trocar, Disposable Optical Trocar and Disposable Bladed Trocar.
510(k) Number: K190029
Regulation Number: 876.1500
Product Code: GCJ
Regulation Class: II
Manufacturer: Changzhou Xin Neng Yuan Medical Stapler Co., Ltd.

4. **Proposed Device Description**

Disposable Trocars are medical devices that penetrate the abdominal wall during laparoscopic surgery. They provide a passageway for the surgical device insertion and removal and maintain pneumoperitoneum during surgical procedures.

The model numbers of Disposable Trocars include AVTB 5-70, AVTB 5-100, AVTB 10-70, AVTB 10-100, AVTB 12-70, AVTB 12-100, AVTC 5-70, AVTC 5-100, AVTC 10-70, AVTC 10-100, AVTC 12-70, AVTC 12-100, AVTC 15-70,

and AVTC 15-100.

The AVTB Disposable Trocars comprise an upper sealing component, a casing component, and a puncture rod component.

The upper sealing component is composed of a seal lid, an upper retaining ring, a wave seal ring, a conical sealing ring, a lower retaining ring, and a retaining cover for locking. The casing component is composed of choke valve, self-commissioning sealing cap, casing seat, seal ring, trocar sleeve, gas injection valve, and gas injection switch. The puncture rod component is composed of an upper fixing cover, a locking buckle, a puncture rod, and a lower fixing cover.

AVTC Disposable Trocars comprise casing component, puncture rod component, upper sealing component, and converter component (only applicable to AVTC 15 specification).

The casing component is composed of choke valve, self-commissioning sealing cap, casing seat, sealing ring, trocar sleeve, gas injection valve, and gas injection switch. The puncture rod component is composed of an upper fixing cover and a puncture rod. The upper sealing component (5/10/12 specification) is composed of seal lid, an upper retaining ring, a wave seal ring, a conical sealing ring, a lower retaining ring, and a retaining cover for locking. The upper sealing component (15 specifications) is composed of a seal lid, an elastic seal ring, and a retaining cover for locking. The converter component (15 specifications) is composed of converter, converter cover, sealing cap of upper converter cover, and upper converter cover.

Disposable Trocars are divided into B and C according to different shapes. According to the inner diameter of the trocar, it is divided into four sizes: 5, 10, 12, and 15. According to the length of the trocar, it is divided into two sizes: 70 and 100.

**5. Indications for use**

The Disposable Trocars have applications in minimally invasive surgical procedures to establish a path of entry for endoscopic instruments in abdominal area.

**6. Technological Characteristics:**

The materials of Disposable Trocars are PE, PC, ABS, and silica gel.

The assembled Disposable Trocars puncture the hole (use a blade to cut a pre-puncture hole) of the abdomen, reach the predetermined position through the

abdominal wall, and then withdraw the puncture rod component, leaving the casing component as the working channel of endoscopic stapler and endoscope.

The gas injection valve is connected to the pneumoperitoneum machine. The choke valve and casing component form a closed space with the human body to maintain the pneumoperitoneum. When the stapler or endoscope is inserted, due to the existence of choke valve, there is basically no air leakage. A little air leakage can be supplemented by pneumoperitoneum machine.

**7. Summary of non-clinical testing:**

The following non-clinical tests, including both bench and *ex vivo*, were conducted to demonstrate that the performance of the proposed device is substantially equivalent to that of the predicate device and to verify that the proposed device met all design specifications. Results of biocompatibility, sterility, and packaging tests demonstrated that the proposed device met its specifications and requirements.

Dimension verification and bench performance test were conducted to demonstrate the essential performance of the proposed device. The results of the tests listed below showed that the subject device is substantially equivalent to the predicate device.

1. Compatible with endoscope and endoscopic stapler
2. Flexibility
3. Parts compatible with each other
4. Airtightness and air resistance
5. Connection strength
6. Luer connector
7. Insertion and pull-out performance of puncture rod
8. Gas leak rate
9. Endotoxin limit test

An *ex vivo* study was conducted on porcine tissue to evaluate the penetration force and fixation force. In addition, tip integrity was evaluated after each insertion.

Shelf-life testing was conducted based on an accelerated aging test in accordance with ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices. The real-time aging study is ongoing to evaluate longer stability and will support the results of the accelerated aging test.

Simulated transport testing was conducted based on ASTM D4169:2022 Standard Practice for Performance Testing of Shipping Containers and Systems and support product and packaging performance

Sterilization validation was conducted in accordance with ISO 11135:2014 using the overkill validation methods to demonstrate the ability to achieve a sterility assurance level of $10^{-6}$.

Biocompatibility testing was performed in accordance with:

FDA Guidance, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process"

ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

ISO 10993-12:2021 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

ISO 10993-11:2017 Biological evaluation of medical devices-Part 8 Tests for systemic toxicity

ISO 10993-23:2021 Biological evaluation of medical devices-PART 23: Tests for irritation

ISO 10993-18:2020 Biological evaluation of medical devices Chemical characterization of medical device materials within a risk management process

Sterility and packaging:
Accelerated aging, simulated transport, product sterility performance, and packaging performance tests were tested according to:

ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

ASTM F88/F88M-23 Standard Test Method for Seal Strength of Flexible Barrier Materials

ASTM F1929-23 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

USP <85> Bacterial Endotoxins Test

**8. Clinical Test Conclusion**

No clinical study is included in this submission.

**9. Substantially Equivalent (SE) Comparison**

Table 1 Comparison of Technology Characteristics

| **Item** | **Proposed Device**<br>Disposable Trocars | **Predicate Device**<br>Disposable Bladeless Trocar, Disposable Optical Trocar and Disposable Bladed Trocar (K190029) |
|---|---|---|
| Classification | II | II |
| Regulation Number | 876.1500 | 876.1500 |
| Product Code | GCJ | GCJ |
| Intended Use | The Disposable Trocars have applications in minimally invasive surgical procedures to establish a path of entry for endoscopic instruments in abdominal area. | The devices, Disposable Bladeless Trocar, Disposable Optical Trocar and Disposable Bladed Trocar, have applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. |
| Configuration | Puncture rod | Puncture needle |

| | Trocar sleeve<br>Converter | Puncture sleeve<br>Reducer cap |
|---|---|---|
| Single Use | Single Use | Single Use |
| Operation Mode | Manually | Manually |
| Accessory | No accessory | Puncture sleeve, reducer cap |
| Safety features | No safety feature | No safety feature |
| Labeling | Comply with 21 CFR section 801 | Comply with 21 CFR section 801 |
| Shaft Diameter | Available in 5 mm, 10 mm, 12 mm, and 15 mm | Available in 3 mm, 5 mm, 8 mm, 10 mm, 12 mm, and 15 mm |
| Shaft Length | Available in 70 mm and 100 mm | Available in 75 mm and 100 mm |
| Material | ABS, PC, PE, colorant,<br>silica gel | ABS, PC, PE, colorant,<br>rubber |
| Trocar Width | 61 mm, 65 mm | 52.4 mm, 61.4 mm |
| Total Length | 151 mm, 194 mm, 204 mm | 158 mm, 184 mm, 172 mm,<br>197 mm |
| Needle Tip<br>Shape | Fin | Fin |
| Sterilization | EO sterilized | EO sterilized |
| SAL | $10^{-6}$ | $10^{-6}$ |

| | | |
|---|---|---|
| Endotoxin Limit | 20 EU per device | 20 EU per device |
| Shelf life | 3 years | 2 years |
| Packaging method | Sealing method | Sealing method |
| Cytotoxicity | No cytotoxicity | No cytotoxicity |
| Sensitization | No sensitization | No sensitization |
| Skin Irritation | No irritation | No irritation |
| Pyrogen | No pyrogen | No pyrogen |

**10. Conclusion:**

The proposed Disposable Trocars are found substantially equivalent to the predicate device. The differences between the proposed and predicate devices do not raise new or different questions of safety and/or effectiveness. The non-clinical performance testing demonstrates that the device is as safe and effective as the legally marketed device.