April 9, 2024

Hangzhou Kangji Medical Instrument Co., Ltd.
% Esther Zhang
Shanghai Ling Fu Technology Co., Ltd.
4F No. 585-2, Wanyuan Rd. Minhang District
Shanghai, Shanghai 201102
China

Re: K233263
Trade/Device Name: Disposable Trocars
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 28, 2023
Received: September 29, 2023

Dear Esther Zhang:

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.

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.04.09 12:02:16 -04'00'

Mark Trumbore, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233263

Device Name

Disposable Trocars

Indications for Use *(Describe)*

The Disposable Trocars have application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments and/or endoscope.

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.

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510(k) summary
K233263

I Submitter

Device submitter: Hangzhou Kangji Medical Instrument Co., Ltd.
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Date: April 9, 2024

II Device

Trade Name of Device: Disposable Trocars
Common Name: Trocars
Regulation Number: 21 CFR 876.1500
Regulation Name: Laparoscope, General & Plastic Surgery
Regulatory Class: II
Product code: GCJ
Review Panel: General and Plastic Surgery

III Correspondent

Shanghai Ling Fu Technology Co., Ltd.
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IV Device description

The Disposable Trocars includes Normal trocars (model A), Balloon trocars (model B), Thread trocars (model C) and Single-port trocars (model E). They are generally composed of cannula and obturator, with or without filter/cleaning ring/protector.

The Disposable Trocars have application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments and/or endoscope. If needed, the CO_2 can be infused through the valve. The product is sterilized by Ethylene oxide and is a single-use product.

Normal trocars have 3 different cannulas (normal cannula, normal cannula with filter, normal cannula with cleaning ring) and 5 different obturators (Ingot-type, Optical obturator A, Optical obturator B, Auto-shielded obturator, Blunt obturator). Normal cannula consists of Cannula Body, Cannula Tube Seat, Choke Valve, Sheath Cap and Stopcock. It may be equipped with a filter or cleaning ring as an accessory. Cleaning ring is equipped inside the cannula and used for removing blood and foreign matter from the laparoscope. Filter is detachable, installed in stopcock, and used for filtering out any

foreign matter that spills out of the body during surgery. Stopcock can be used for insufflation if needed. Ingot-type obturator is easy to insertion which consists of Needle Tip, Needle Tube and Needle Seat. Optical obturator A has a transparent needle tip while Optical obturator B has a transparent needle tip and needle tube. Needle tube of these two optical obturators is hollow which allows laparoscope go inside to see if it has passed the abdominal wall. Auto-shielded obturator has a hided blade which only showing up in puncturing process. Blunt obturator has a blunt needle tip which can protect internal organ during the procedure. Normal trocars are available from 3-15mm of diameter and 65-160mm of length.

Balloon Trocars are equipped an inflatable balloon with a fixed (Balloon cannula A) or movable holder (Balloon cannula B) to provide stabilization during a laparoscopic procedure. The Cannula consists of Balloon, Cannula body, Holder A, One-way vale, Cannula Tube Seat, Stopcock, Sheath Cap and Choke Valve. Stopcock can be used for insufflation if needed. Movable holder can be slid down to adjust its height at a desired position for stabilization. There are five different obturators as same as normal trocars: Ingot-type, Optical obturator A, Optical obturator B, Auto-shielded obturator, Blunt obturator. Balloon Trocars are available in from 3-15mm of diameter and 55-140mm of length.

Thread trocars consists of a thread obturator and a Thread cannula A (thoracic trocars) or B (Orthopedics trocars). Threaded cannula enhances stability when exchanging instruments. Thread cannula B consists of Cannula body, Cannula Tube Seat, Stopcock, Sheath Cap and Choke Valve while Thread cannula A does not have a stopcock. Stopcock can be used for insufflation if needed. Thoracic trocars are available in from 5-20mm of diameter and 65-85mm of length. Orthopedics trocars are designed for Orthopedics laparoscopic surgery and available in from 5-20mm of diameter and 65-120mm of length.

Single-port Trocars are designed to provide access for multiple instruments and/or endoscope to the abdominal cavity through a single incision during minimally invasive endoscopic surgery. It consists of cannula, universal seal system, a variable height protector or fixed height protector, with or without obturator. Single port cannula A and B use same materials and only different in shapes. Universal seal system A supports the free combination and arrangement of trocar with different numbers and sizes to meet different surgical needs. Obturator is used with Single port cannula A. Universal seal system B is fully transparent and visible for surgical operation. Besides, soft material makes it good for handling the endoscopic instruments and reducing surgical compression congestion to the patient skin. Universal seal system C has a larger handling space than system B. Protector, which has fixed height or variable height, is used for protect surgical incision.

Due to the different structure and function, diameter, length of the Cannula and Obturator, and package amount, there are many combinations for final product.

V Indications for use

The Disposable Trocars have application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments and/or endoscope.

VI Substantial Equivalence

The proposed Disposable Trocars are substantially equivalent to the predicate devices:

Model of proposed device	Predicate device	Manufacturer	510(k) No.
K112358	Unimax Trocar System	Unimax Medical Systems Inc.	GCJ
K211577	SoftFix™ Balloon Trocar	Unimax Medical Systems Inc.	GCJ
K141715	Glove Port	NELIS	OTJ
K093372	SILS™ Port	COVIDIEN LP	GCJ
K073719	ASC TriPort Laparoscopic Access Device	Advanced Surgical Concepts.	GCJ

Comparison of technological characteristics with the predicate devices

Table 1 Substantial equivalence discussion- Model A/B/C

Device feature	Subject Device (Model A/B/C)	Predicate Device K112358 (Unimax Trocar System)	Predicate Device K211577 (SoftFix™ Balloon Trocar)	Comment
Class	II	II	II	Equivalent
Product code	GCJ	GCJ	GCJ	Equivalent
Regulation number	21 CFR 876.1500	21 CFR 876.1500	21 CFR 876.1500	Equivalent
Intended use	The Disposable Trocars have application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments and/or endoscope.	The Unimax Trocar System, Model: Auto-Locking Trocar, Bladeless Trocar, Visible Trocar, Hasson Trocar, Dilating Trocar Secondary Trocar, and Thoracic Trocar has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments.	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.	Equivalent.
Models	Normal trocars (Model A)	Bladeless, Visible and auto-locking, Secondary trocars	/	Different Comment 1
	Balloon trocars (Model B)	Hasson trocars	Balloon trocar (bladed obturator with safety lock for the shield, bladeless obturator, optical obturator, hasson obturator, cannula sleeve with a stopcock for insufflation)	
	Thread trocars (Model C)	Thoracic trocars	/	

	/	Dilating trocars	/	
Device structure	Cannula with or without cleaning ring/filter, balloon cannula, cannula with stopcock for insufflation, obturator	Cannula with stopcock for insufflation, obturator	Cannula with a stopcock for insufflation, obturator	
Specification	Diameter: 3-15mm Length: 60-160mm	Diameter: 3-15mm Length: 65-150mm	Diameter: 5-12mm Length: 70-100mm	Similar Comment 2
Reuse durability	Single use	Single use	Single use	Equivalent
Sterilization	EO	EO	EO	Equivalent
Single use	Yes	Yes	Yes	Equivalent
Performance	Obturator Compatibility; Insertion & Cannula Stability; Air Leakage; balloon rigidity; fixation device retention	Obturator Compatibility; Insertion&Cannula Stability; Air Leakage	Obturator Compatibility; Insertion & Cannula Stability; AirLeakage; balloon rigidity; fixationdevice retention	Equivalent
Biocompatibility	ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-7, ISO 10993-12	ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-7, ISO 10993-12	ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-7, ISO 10993-12	Equivalent

Discussion:

Comment 1

The subject device and the predicate device have the same intended use, to applicate in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments. The obturator and cannula have miner difference on needle tip and cannula accessories (e.g. cleaning, filter), while these differences have been validated by performance test and do not influence their intended use. This difference does not affect the clinical safety of the subject device.

Comment 2

The Disposable Trocars are available in a range of Length. This variation in length is only to allow entry of other endoscopic instruments and does not have any effect on device performance. Additionally, length information is printed on the Obturator. Choice of Trocar specification depends on user's preference and clinical need. The differences on length do not raise new questions about safety and effectiveness.

Conclusion:

The Disposable Trocars (Model A/B/C) have the same intended use, technology, design and performance specifications are either identical or substantially equivalent to existing legally marketed predicate devices. The differences between the subject device and predicate devices do not alter suitability of the proposed device for its intended use.

Table 2 Substantial equivalence discussion-Single-port trocars (Model E)

Device feature	Subject Device (Model E Single-port Trocars)	Predicate DeviceK141715 (Glove Port)	Predicate DeviceK093372 (SILS™ Port)	Predicate DeviceK073719 (ASC TriPort Laparoscopic Access Device)	Comment
Class	II	II	II	II	Equivalent
Regulation number	21 CFR 876.1500	21 CFR 876.1500	21 CFR 876.1500	21 CFR 876.1500	Equivalent
Intended use	The Disposable Trocars have application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments and/orendoscope. Single-port Trocars are designed to provide access for multiple instruments and/or endoscope to the abdominal cavity through a single incision during minimally invasive endoscopic surgery.	The Glove Port is intended to provide access for multiple instruments and/or endoscope to the abdominal cavity through a single incision during minimally invasive laparoscopic surgery.	The SILS™ Port is indicated for multiple instrument or camera access to the abdominal cavity through a singleincision for performingminimally invasive laparoscopic procedures.	The ASC TriPort Laparoscopic Access Device is intended foruse as a multiple instrument and/or camera port during minimally invasive abdominal laparoscopic surgery.	Equivalent

Model	E01, E02, E03, E04, E05, E06, E07, E08	Glove Port Original; Glove Port H; Glove Port A; Glove Port AT	SILS™ Port	ASC TriPort Laparoscopic Access Device	Similar Comment 1
Port number	3~4	3~4	3~4	3	
Absolute size	10~25	10~25mm	10~25mm	25mm	
Material	Polycarbonate, silicone	Polyurethane	Silicone	Silicone	Different Comment 2
Installation and abdominal wall inner fixation	Inner ring of the protector being fixed inside the abdominal wall inside.	Wound retractor ring being fixed inside the abdominal wall inside.	Distal ring being fixed in the abdominal wallinside.	Non-fixed	Equivalent
Sterilization	EO gas sterilization	EO gas sterilization	Gamma sterilization	Gamma sterilization	Different Comment 3

Discussion:

Comment 1

The subject device and the predicate devices are endoscopic instrument access ports that are used to perform the same function as a trocar. They are all retracts a small abdominal incision to allow endoscopic instruments to pass through to abdomen, and maintains pneumoperitoneum in the abdomen during the surgical procedure, whether or not endoscopic instruments are passing through the port. The difference in models, port number and size will not influence their intended use. Besides, surgeons will select port number and size based on actual needs during procedure. Furthermore, these differences have been addressed by performance test and do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety.

Comment 2

The materials of the subject device and the predicate devices are partially different. However, the materials have been tested according to ISO 10993 series standards and performance test. The results showed they're biocompatible with human body and no impact of air leakage, connection firmness, Cannula stabilization and other functions. This difference does not affect the effectiveness and safety.

Comment 3

The sterilization method of the subject device and the predicate devices are partially different. However, the subject device was ensured sterility by sterilization validation. Therefore, the differences on sterilization do not raise new questions about safety and effectiveness.

Conclusion:

The Disposable Trocars (Model E) have the same intended use, technology, design and performance specifications are either identical or substantially equivalent to existing legally marketed predicate devices. The differences between the subject device and predicate devices do not alter suitability of the proposed device for its intended use.

Comparison Summary:

The subject and predicate devices have the same intended use and application. The subject and predicate device designs are similar. They are single-use devices. The differences in technological characteristics between the subject and predicate devices (i.e., needle tip, different size, port number) do not raise different questions of safety and effectiveness.

VII Summary of non-clinical testing

Performance testing

The Disposable Trocars has been evaluated by our Design Engineer and through performance studies and bench testing, as attached in Appendix C. Testing encompassed appearance, Obturator Compatibility, Insertion & Cannula Stability, Air Leakage, balloon rigidity, fixation device retention, etc. All the test results were "PASS". The performance of Disposable Trocars meets the technical standard requirements of Hangzhou Kangji Medical Instrument Co., Ltd. as compared to the predicate.

Biocompatibility testing

Biocompatibility of the Disposable Veress needles was evaluated in accordance with ISO 10993-1:2018 for the body contact category. The following tests were performed, as recommended:

Cytotoxicity	ISO 10993-5:2009
Sensitization	ISO 10993-10:2021
Irritation	ISO 10993-23:2021
Acute Systemic toxicity	ISO 10993-11:2017
Pyrogenicity	USP<151>

Sterilization and shelf life testing

- EO sterilization validation per EN ISO 11135-1, 11737-1,11737-2
- Transportation test per ASTM D4169
- Packaging validation per ISO 11607-1/-2
- The 3 years shelf life of the device is determined based on stability study which includes ageing test.
- Bacterial Endotoxin Testing per USP-NF:2023 <85>

VIII Conclusion

The Disposable Trocars is substantially equivalent to its predicate devices as listed in **VI Substantial Equivalence**. The differences between the predicate and subject device do not raise any new or different questions of safety or effectiveness. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.