November 7, 2023

Jiangsu Channel Medical Device Co., Ltd
% Jarvis Wu
Senior Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Building, 1500# Century Ave
Shanghai 200122
China

Re: K232866
Trade/Device Name: Disposable Abdominal Trocars (Bladed Trocars, Bladeless Trocars, Optical Trocars)

Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 15, 2023
Received: September 15, 2023

Dear Mr. Wu:

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: 2023.11.07 08:42:27 -05'00'

Mark Trumbore, Ph.D.
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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)*
K232866

Device Name
Disposable Abdominal Trocars (Bladed Trocars, Bladeless Trocars, Optical Trocars)

Indications for Use *(Describe)*
The Disposable Abdominal Trocars (Bladed Trocars, Bladeless Trocars, Optical Trocars) is used to puncture the abdominal wall of human body during laparoscopy and operation to establish the working channel for abdominal surgery.

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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K232866

510(K) Summary

Document prepared date: 2023/11/04

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B. Device:

Trade Name: Disposable Abdominal Trocars (Bladed Trocars, Bladeless Trocars, Optical Trocars)
Common Name: Disposable Surgical Trocar /Cannula

Regulatory Information
Classification Name: Laparoscope, General & Plastic Surgery
Classification: Class II
Product code: GCJ
Regulation Number: 876.1500

C. Predicate device:

Primary Predicate Device: K141594
Product name: Unimicro Trocar kit
Model: Auto-Locking Trocar, Hasson Trocar, Bladeless Trocar.
Unimicro Medical Systems (ShenZhen) Co., Ltd.

Secondary Predicate Device: K172038
Product name: Trocar,
Model: Auto-Locking Trocar, Bladeless Trocar, Visible Trocar

WickiMed (Huizhou) Medical Equipment Manufacturing Co.,Ltd.

D. Intended use of the device:

The Disposable Abdominal Trocars (Bladed Trocars, Bladeless Trocars, Optical Trocars) is used to puncture the abdominal wall of human body during laparoscopy and operation to establish the working channel for abdominal surgery.

E. Device Description:

The Disposable Abdominal Trocars (Bladed Trocars, Bladeless Trocars, Optical Trocars) are available in total of eight (8) sizes.

The Disposable Abdominal Trocars (Bladed Trocars), knows as Auto-Locking Trocar, has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments. The Disposable Abdominal Trocars (Bladed Trocars) is available in three (3) sizes: 5mm, 10mm and 12mm. The cannula assembly has a universal seal, a valve, and a stopcock. This device has a bladed tip with an internal shield, which is designed to cover the cutting edges once the body cavity has been entered.

The Disposable Abdominal Trocars (Bladeless Trocars) has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments. The Disposable Abdominal Trocars (Bladeless Trocars) is available in one (1) size: 5mm.

The Disposable Abdominal Trocars (Optical Trocars), knows as Visible Trocar, has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments. This device has a blunt tip, which is designed for open Laparoscopy. The Disposable Abdominal Trocars (Optical Trocars) is available in four (4) sizes: 5mm, 10mm, 12mm and 15mm. This device allows direct visualization of the abdominal wall layers when the trocar is traversed, which offers a safe and rapid option of primary trocar. The cannula assembly has a universal seal, a valve and a stopcock.

Based on the filter valve, the Disposable Abdominal Trocars (Bladed Trocars, Bladeless Trocars, Optical Trocars) are divided into two (2) product series: CNTCI series without smoke evacuation function and CNTCII series with smoke evacuation. The cannula consists of sleeve, stopcock valve, valve lever, gas check valve and lip seal. The obturator consists of fixed base, obturator tube and obturator tip. There are various specifications available depending on the inner diameter and length of sleeve.

F. Comparison with predicate device

Device	**Subject Device**	**Primary Predicate Device**	**Secondary Predicate Device**
Manufacturer	Jiangsu Channel Medical Device Co., Ltd.	Unimicro Medical Systems (ShenZhen) Co., Ltd.	WickiMed (Huizhou) Medical Equipment Manufacturing Co.,Ltd.
510K number	K232866	K141594	K172038
Product Name	Disposable Abdominal Trocars	Unimicro Trocar kit	Trocar

Classification		Class II Device (21 CFR 876.1500)	Class II Device (21 CFR 876.1500)	Class II Device (21 CFR 876.1500)
Intended use		The Disposable Abdominal Trocars (Bladed Trocars, Bladeless Trocars, Optical Trocars) is used to puncture the abdominal wall of human body during laparoscopy and operation to establish the working channel for abdominal surgery.	The Unimicro Trocar kit, Model: Auto-Locking Trocar, Hasson Trocar, and Bladeless Trocar has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments.	The Trocar Models: Auto-Locking Trocar, Bladeless Trocar and Visible Trocar, has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments.
Principles of operation		Trocar inserted into the skin incision, and punctured into the abdominal cavity. Removed the puncture cone and made a surgical channel.	Trocar inserted into the skin incision, and punctured into the abdominal cavity. Removed the puncture cone and made a surgical channel.	Trocar inserted into the skin incision, and punctured into the abdominal cavity. Removed the puncture cone and made a surgical channel.
Model		Auto-Locking Trocar (Bladed Trocar)	Auto-Locking Trocar	/
		Bladeless Trocar	Bladeless Trocar	/
		Visible Trocar (Optical Trocar)	/	Visible Trocar
Mainly Structure		Cannula, (blade), universal seal, valve, stopcock	Cannula, (blade), universal seal, valve, stopcock	Cannula, (blade), universal seal, valve, stopcock
Specification		Diameter :5-15mm	Diameter :5-12mm	Diameter :5-12mm
		Length :110-150mm	Length: 70-120mm	Length :100mm
Patient-contacting structure	**ATR**	Blade, Cutting head, Cannula	Blade, Cutting head, Cannula	Blade, Cutting head, Cannula
	BTR	Cutting head, Cannula	Cutting head, Cannula	Cutting head, Cannula
	VTR	Cutting head, Cannula	/	Cutting head, Cannula
Patient-contacting Materials	**ATR**	Stainless Steel, PC	Stainless Steel, PC, ABS	Stainless Steel, PC, ABS
	BTR	PC,	PC, ABS	PC, ABS
	VTR	PC	/	PC
Safety standards		ISO 10993-1 ISO 10993-5 ISO 10993-7 ISO 10993-10 ISO 10993-11 ISO 10993-12 ISO 10993-23 ISO 11135	ISO 10993-1 ISO 10993-5 ISO 10993-7 ISO 10993-10 ISO 10993-12 ISO 11135-1	ISO 10993-1 ISO 10993-5 ISO 10993-7 ISO 10993-10 ISO 10993-11 ISO 10993-12 ISO 11135

Performance testing items	Obturator compatibility	Obturator compatibility	Obturator compatibility
	Insertion & cannula stability	Insertion & cannula stability	Insertion & cannula stability
	Air leakage	Air leakage	Air leakage
	Trocar Insertion/ Removal force	Trocar Insertion/ Removal force	Trocar Insertion/ Removal force
Sterilization	EO Sterilized	EO Sterilized	EO Sterilized
Disposable	Yes	Yes	Yes

Different analysis:

The subject and predicate devices have the similar intended use. The subject and predicate devices designs are nearly identical. Both are single-use devices, and structure and technology characteristic are identical. The differences in specification and patient-contacting materials between the subject and predicate devices do not raise conc questions of safety and effectiveness.

G. Non-Clinical Testing

A series of tests were performed to assess the safety and effectiveness of the Disposable Abdominal Trocars (Bladed Trocars, Bladeless Trocars, Optical Trocars). Biocompatibility tests were conducted in accordance with ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-7:2008, ISO 10993-10:2021, ISO 10993-11:2017, ISO 10993-12:2021 and ISO 10993-23:2021. The biocompatibility tests included Cytotoxicity, Sensitization, Intracutaneous reactivity, Acute systemic toxicity and Material-Mediated Pyrogenicity. Sterilization validation was performed per ISO 11135:2014.

The performance testing conducted on subject device and predicate devices are listed below:

- Obturator Compatibility
- Insertion & Cannula Stability
- Air Leakage
- Trocar Insertion/ Removal force

All the test results demonstrate Disposable Abdominal Trocars (Bladed Trocars, Bladeless Trocars, Optical Trocars) meet the requirements of its pre-defined acceptance criteria and intended uses.

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

Based on the comparison and analysis above, the subject device Disposable Abdominal Trocars (Bladed Trocars, Bladeless Trocars, Optical Trocars), is as safe, as effective, and performs as well as the legally marketed predicate devices.