June 8, 2023

Changzhou Ankang Medical Instruments Co., Ltd.
% Ms. Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K231042
Trade/Device Name: Disposable Laparoscopic Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: April 11, 2023
Received: April 12, 2023

Dear Ms. Hong:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 2023.06.08 09:51:47 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231042

Device Name
Disposable laparoscopic trocar

Indications for Use *(Describe)*
The disposable laparoscopic trocar has applications in abdominal and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments.

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

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

The assigned 510(k) Number: K231042

1. Date of Preparation: 06/07/2023

2. Sponsor Identification

Changzhou Ankang Medical Instruments Co., Ltd.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
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4. Identification of Proposed Device

Trade Name: Disposable laparoscopic trocar
Common Name: Disposable Trocar/Cannula

Regulatory Information

Classification Name: laparoscope, general & plastic surgery
Classification: II;
Product Code: GCJ;
Regulation Number: 21 CFR 876.1500
Review Panel: General & Plastic Surgery;

Indications for Use:

The disposable laparoscopic trocar has applications in abdominal and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments.

Device Description:

The proposed devices are available in two types, bladeless type and bladed type, which consist of puncture needle, puncture sleeve, injection valve and sealing cover. In order to obtain access to the surgical site during laparoscopic surgery, the puncture needle is introduced into puncture sleeve to accomplish cannula penetration of the abdominal wall. The sleeve is connected to the injection valve at its proximal end and once the abdominal/thoracic wall is punctured, the puncture needle is removed. The sleeve acts as a channel for the introduction of the endoscopes and instruments. The bladeless type disposable laparoscopic trocar is available in 5mm, 10mm, 12mm and 15mm four diameters, and the bladed type disposable laparoscopic trocar is available in 5mm, 10mm and 12mm three diameters to accommodate different sizes surgical instrument.

5. Identification of Predicate Device

510(k) Number: K190029
Product Name: Disposable Bladeless Trocar, Disposable Optical Trocar and Disposable Bladed Trocar

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was same/similar to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-7: 2008 Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals;
- USP <85> Bacterial Endotoxin Limit
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems
- ISO 10993-5: 2009 Biological Evaluation of Medical Devices-Part 5: Tests for in Vitro Cytotoxicity;
- ISO 10993-10: 2010 Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization;
- ISO 10993-11:2017 Biological evaluation of medical devices -Part 11: Tests for systemic toxicity
- USP <151> Pyrogen Test (USP Rabbit Test)

Bench tests were conducted on the proposed device and predicate device, which include

- Instrument Insertion and Removal Forces Test
- Leak Resistance Test
- Snap Feature Retention Force Test

An in vivo study was conducted on both proposed device and predicate device, it was tested on a porcine model to evaluate the penetration force and fixation force. In addition, visual inspection was performed to check the device integrity after the trocar was removed.

Biocompatibility tests were conducted on the proposed device, the test items include Cytotoxicity test, Intracutaneous Reactivity test, Skin Sensitization test, Acute System Toxicity test and Pyrogen Test.

Sterilization and sterile barrier package testing were performed on the proposed device, which include

- EO and ECH residue test
- Endotoxin Limit test
- Visual Inspection
- Seal Strength
- Dye Penetration
- Simulated Distribution

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Summary of Technological characteristics

Table 1 Comparison of Disposable Bladeless Trocar

Item	Proposed Device	Predicate Device K190029 Disposable Bladeless Trocar	Remark
Product Code	GCJ	GCJ	Same
Regulation No.	21 CFR 876.1500	21 CFR 876.1500	Same
Class	II	II	Same
Indications for Use	The disposable laparoscopic trocar has applications in abdominal and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments.	The device has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments.	Different 1
Configuration	Puncture Needle Sheath Puncture Sleeve Protection Fixed Seat	Puncture Needle Puncture Sleeve Reducer Cap	Different 2
Single Use	Single Use	Single Use	Same
Operation Mode	Manually	Manually	Same
Safety features	No safety feature	No safety feature	Same
Label/Labeling	Comply with 21, CFR Section 801	Comply with 21, CFR Section 801	Same
Shaft Diameter	Available in 5, 10, 12 and 15mm	Available in 3, 5, 8, 10, 12, and 15mm	Different 3
Shaft Length	Available in 100mm	Available in 75 and 100mm	
Patient Contacting component	Puncture Needle Puncture Sleeve	Puncture Needle Puncture Sleeve	Same
Patient Contacting Material	PC, ABS, Stainless Steel	ABS	Different 4
Sterilization			
Method	EO sterilized	EO sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same
Shelf Life	3 years	2 years	Different 5
Packaging method	Sealing method	Sealing method	Same
Biocompatibility			
Cytotoxicity	No cytotoxicity	No cytotoxicity	Same

Intracutaneous Reactivity	No intracutaneous reactivity	No intracutaneous reactivity	
Sensitization	No sensitization	No sensitization	
Acute System Toxicity	No acute system Toxicity	/	
Pyrogen	No pyrogen	No pyrogen	

Table 2 Comparison for Disposable Bladed Trocar

Item	Proposed Device	Predicate Device K190029 Disposable Bladed Trocar	Remark
Product Code	GCJ	GCJ	Same
Regulation No.	21 CFR 876.1500	21 CFR 876.1500	Same
Class	II	II	Same
Indication for Use	The disposable laparoscopic trocar has applications in abdominal and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments.	The device has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments.	Different 6
Configuration	Puncture Needle Sheath Puncture Sleeve Protection Fixed Seat Blade	Puncture Needle Puncture Sleeve Reducer Cap Puncture Knife	Different 7
Single Use	Single Use	Single Use	Same
Operation Mode	Manually	Manually	Same
Label/Labeling	Comply with 21, CFR Section 801	Comply with 21, CFR Section 801	Same
Shaft Diameter	Available in 5, 10 and 12mm	Available in 5, 8, 10 and 12mm	Different 8
Shaft Length	Available in 100mm	Available in 75 and 100mm	
Patient Contacting component	Puncture Needle Puncture Sleeve Blade	Puncture Needle Puncture Sleeve Puncture Knife	Same
Patient Contacting Material	PC, ABS, Stainless Steel	ABS, Stainless Steel	Different 9
Sterilization			
Method	EO sterilized	EO sterilized	Same
SAL	10^{-6}	10^{-6}	Same

Endotoxin Limit	20 EU per device	20 EU per device	Same
Shelf Life	3 years	2 years	Different 10
Packaging method	Sealing method	Sealing method	Same
Biocompatibility			
Cytotoxicity	No cytotoxicity	No cytotoxicity	Same
Intracutaneous Reactivity	No intracutaneous reactivity	No intracutaneous reactivity	
Sensitization	No sensitization	No sensitization	
Acute System Toxicity	No acute system Toxicity	/	
Pyrogen	No pyrogen	No pyrogen	

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and perform as well as or better than the legally marketed predicate device K190029.