July 9, 2020

Guangzhou TK Medical Instrument Co., Ltd.
% Elly Xu, Consultant Manager
Shenzhen Joyantech Consulting Co., Ltd
No. 55 Shizhou Middle Road, Nanshan District
Shenzhen, Guangdong
China 518000

Re: K193272
Trade/Device Name: GTK Trocars
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 26, 2020
Received: July 6, 2020

Dear Elly Xu:

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 and Part 809); 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,

Long Chen, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193272

Device Name
GTK Trocars

Indications for Use *(Describe)*
The GTK Trocars has an application in a variety of endoscopic procedures to provide a port for 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.

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510(k) Summary

1. Submission Sponsor

Applicant Name	Guangzhou T.K. Medical Instrument Co., Ltd.
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Phone No.	86-20-32290169
Fax No.	86-20-32290395
Contact Person	Ms. Tracy Weng
Date Prepared	July 9, 2020

2. Submission correspondent

Name	Shenzhen Joyantech Consulting Co., Ltd
Address	Room 1122, No.55 Shizhou Middle Road, Nanshan District, Shenzhen, Guangdong, P.R. China
Post Code	518000
Phone No.	86-755-86069197
Contact Person	Field Fu; Elly Xu
Email	elly@cefda.com

3. Devices Identification

Trade name	GTK Trocars
Common name	Trocar
Model	CT
Classification	II
Classification name	Endoscope and accessories
Regulation number	876.1500
Product code	GCJ
510(k) review panel	General & Plastic Surgery
Performance standards	Biocompatibility tests were done in conformance with relevant requirements of ISO10993.

4. Legally Marketed Predicate Devices

Trade Name	Unimax Trocar System
Regulation number	876.1500

Regulation class	II
Regulation name	Endoscope and accessories
510(k) Number	K112358
Product Code	GCJ
Manufacturer	Unimax Medical Systems Inc.

5. Device Description

The GTK Trocars has an application in a variety of endoscopic procedures to provide a port for entry for endoscopic instruments. The available model of the Trocar is model CT.

All the trocars have the similar structure. They are composed of cannula, stopcock, trocar cap, and obturator. The trocar cap has a universal seal which accommodates instruments of different diameters. The cannula has a valve which ensures the sealing performance.

The CT trocar consists of an obturator assembly and a cannula assembly. The obturator assembly can be assembled with the cannula assembly by indicator fitting. And Model CT includes CT bladeless trocar, CT optical trocar, and CT bladed trocar.

6. Indications for Use Statement

The GTK Trocars has an application in a variety of endoscopic procedures to provide a port for entry for endoscopic instruments.

7. Substantial Equivalence Discussion

7.1 Comparison between proposed device and Unimax Trocar System

Item	**Proposed Device: GTK Trocars**	**Predicate Device: Unimax Trocar System (K112358)**	**Comments**
Product Code	GCJ	GCJ	Same
Indication for Use	The GTK Trocars has an application in a variety of endoscopic procedures to provide a port for entry for endoscopic instruments	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.	Same
Device Structure	Cannula, obturator	Cannula, obturator	Same
Principles	Trocar is inserted into the skin incision, and punctured into the abdominal cavity. Removed the obturator and make a surgical port for entry.	Trocar is inserted into the skin incision, and punctured into the abdominal cavity. Removed the puncture cone and made a surgical port for entry.	Same
Model	CT Bladeless Trocar	Bladeless Trocar	Same

Item		Proposed Device: GTK Trocars	Predicate Device: Unimax Trocar System (K112358)	Comments
		CT Optical Trocar	Visible Trocar	Same
		CT Bladed Trocar	Auto-locking Trocar	Same
		/	Hasson Trocar	/
		/	Dilating Trocar	/
		/	Secondary Trocar	/
		/	Thoracic Trocar	/
Size		Diameter: 3~12mm Length: 55~100mm	Diameter: 3~15mm Length: 65~150mm	Similar Issue 1
Sterilization		SAL: 10^{-6}	SAL: 10^{-6}	Same
		Method: EO Sterilized	Method: EO Sterilized	Same
Performance		Obturator Compatibility; Insertion & Cannula Stability; Air Leakage	Obturator Compatibility; Insertion & Cannula Stability; Air Leakage	Same
Single Use		Yes	Yes	Same
Biocompatibility	Cytotoxicity	ISO 10993-5:2009	ISO 10993-5:2009	Same
	Sensitization, irritation	ISO 10993-10:2010	ISO 10993-10:2010	Same
	Systemic toxicity	ISO 10993-11:2006	ISO 10993-11:2006	Same

Issue 1: The diameter of proposed device is covered in predicate device. Regarding to the length, the proposed device has a shorter length, which won't bring in safety issue and may provide more choice to the users.

8. Non-clinical Testing

All nonclinical tests performed on new devices are to demonstrate the substantial equivalence to the predicate devices. Tests setup and execution are performed in accordance with applicable standards.

Biocompatibility testing

The biocompatibility evaluations were conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process", as recognized by FDA. The tests of GTK Trocars include the following tests:

* Cytotoxicity
* Sensitization & irritation
* Acute systemic toxicity
* Pyrogen test
* Endotoxin Test

Bench testing

The following bench tests were conducted with the GTK Trocars to verify that the proposed device met all design specifications:

* Appearance
* Dimensions
* Endoscope visualization image quality
* Obturator compatibility
* Insertion & Cannula stability
* Insertion force & Removal force
* Penetration force
* Leak rate

Animal study

To demonstrate the operation performance is as safe and as effective as the predicate device, the animal study was carried out to assess the following performance criteria:

* Ability to access abdominal cavity
* Ability to maintain Pneumoperitoneum
* Ability to manipulate instruments for laparoscopic surgery

Summary

All the testing results, including bench tests, biocompatibility tests and animal study, demonstrate that GTK Trocars meets the requirements of its pre-defined acceptance criteria and intended uses, and it has a safety and effectiveness profile that is similar to the predicate device.

9. Clinical Testing

Substantial equivalence does not depend on clinical test data.

10. Conclusions

Based on device comparison information and non-clinical bench testing, GTK Trocars and its predicate device have the same indications for use, same structures, similar specifications, and same performance. The bench tests, biocompatibility tests and animal study support that the proposed device is as safety and effectiveness as predicate device, and the differences between them will not raise any safe and effective issue. Therefore the proposed device is substantially equivalent to legally marketed predicate device.