January 30, 2020

Guangzhou T.K Medical Instrument Co., Ltd.
℅ Christy Young
Consultant
Shenzhen Joyantech Consulting Co., Ltd
1713A, Block A, Zhongguan Times Square, Liuxian Avenue
Xili Town, Nanshan District, Shenzhen
Guangdong Province, 518000
CHINA

Re: K193339
Trade/Device Name: GTK Veress Needles
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF, FHO
Dated: December 2, 2019
Received: December 2, 2019

Dear Christy Young:

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,

for Sharon M. Andrews
Acting Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K193339

Device Name
GTK Veress Needles

Indications for Use *(Describe)*
The GTK Veress Needles are intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.

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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Contact Person	Ms. Tracy Weng
Date Prepared	1-28-2020

2. Submission correspondent

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Post Code	518000
Phone No.	86-755-86069197
Contact Person	Ms. Christy Young; Field Fu
Email	christy@cefda.com;

3. Devices Identification

Trade Name	GTK Veress Needles
Common Name	Veress Needle
Model Names	VN-120 and VN-150
Regulatory Class	II
Classification Name	Laparoscopic insufflator
Classification Number	21 CFR 884.1730
Product Code	HIF; FHO
Product Code Name	Insufflator, Laparoscopic; Pneumoperitoneum Needle
510(k) review panel	Obstetrics/Gynecology; Gastroenterology/Urology

4. Legally Marketed Predicate Devices

Trade Name	Veress Needle
Classification Number	21 CFR 884.1730
Classification Name	Laparoscopic insufflator
Regulatory Class	II
510 (k) number	K172120
Product Code	HIF; FHO
Product Code Name	Insufflator, Laparoscopic; Pneumoperitoneum Needle
Manufacturer	WickiMed (Huizhou) Medical Equipment Manufacturing Co., Ltd.

The predicate device was not subject to a design-related recall.

5. Legally Marketed Reference Devices

Trade Name	Medline Pneumoperitoneum Needle
Classification Number	21 CFR 884.1730
Classification Name	Laparoscopic insufflator
Regulatory Class	II
510 (k) number	K111955
Product Code	HIF; FHO;
Product Code Name	Insufflator, Laparoscopic; Pneumoperitoneum Needle
Manufacturer	Medline Industries, Inc

The reference device was not subject to a design-related recall

6. Device Description

The structure of the GTK Veress Needles contain inner needle, outer needle, warning block, spring, handle and valve. It contains a spring-loaded blunt stylet mechanism, which is also the major principle mechanism of GTK Veress Needles to achieve the intended use. It is used to establish pneumoperitoneum prior to trocar and cannula insertion in laparoscopic procedures. The veress needle is connected to the insufflators with a luer connector. There are two models of veress needles: VN-120 and VN-150, with different lengths of needle bodies (120mm and 150mm).

The GTK Veress Needles are for single use and are supplied sterile. The contact time is no more than 24 hours. The product is sterilized by Ethylene oxide. The manufacture date and expiry date are shown on the labeling. The GTK Veress Needles are only intended for use in a hospital setting/environment.

7. Indications for Use Statement

The GTK Veress Needles are intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish

pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.

8. Substantial Equivalence Discussion

Table 1: Substantial equivalence comparison

Items	Proposed device		Predicate device		Comments
Trade name	GTK Veress Needles		Veress Needle		/
510(K) submitter	Guangzhou T.K Medical Instrument Co., Ltd.		WickiMed (Huizhou) Medical Equipment Manufacturing Co., Ltd.		/
510(K) number	/		K172120		/
Classification regulation	21CFR 884.1730		21CFR 884.1730		Same
Classification and product code	Class Ⅱ, HIF,FHO		Class Ⅱ, HIF,FHO		Same
Common name	Veress Needle		Veress Needle		Same
Intended use	The GTK Veress Needles are intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.		The Veress Needle is intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.		Same
Components	Veress Needle Obturator		Veress Needle Obturator		Same
Model	VN-120 and VN-150		WVN0112T, WVN0115T		/
Length	120mm,150mm		120mm,150mm		Same
Sterilization	EO Sterilized		EO Sterilized		Same
Disposable	Yes		Yes		Same
Materials	Patient-contacting Material (Outer tube inner tube)	SUS 304	Patient-contacting Material (Outer tube inner tube)	SUS 304	Same

	Handle material	PC	Handle material	PC	Same
Principles of operation	Connect the device to the insufflators with insufflation tubing, insufflating with carbon dioxide to establish pneumoperitoneum.		Connect the device to the insufflators with insufflation tubing, insufflating with carbon dioxide to establish pneumoperitoneum.		Same

9. Non-Clinical Performance Data

1) Biocompatibility test

The needle (inner and outer) of the GTK Veress Needles are contacting with abdominal skin and abdominal wall tissue of human for less than 24 hours. The following tests were conducted:
ISO 10993-5: 2009-In Vitro Cytotoxicity test;
ISO 10993-10: 2010-Skin Sensitization test and Intracutaneous reactivity test;
ISO 10993-11: 2006- Acute systemic toxicity and Pyrogen test;
USP 39 <85>-Bacterial endotoxin test.

2) Sterilization validation

The sterilization validation was conducted according to ISO 11135:2014. The EO and ECH residual of the proposed device was evaluated by ISO 10993-7:2008.

3) Shelf life validation test

The package verification test on proposed devices were conducted after accelerated aging for 3 years (ASTM F 1980-07 (2011)):
ISO 11737-2:2009-sterility test;
ASTM D 3078-02:2013-vacuum leak test;
ASTM F 88-seal strength test;
ASTM F 1929-12-leakage (dye penetration test);
Din 58953-6:2010-microbial barrier properties (agar contact-attack test);
And physical performance of the proposed device was conducted after natural aging. All the results meet the acceptance criteria.

4) Performance test-bench

The performance tests of GTK Veress Needles contain appearance, size, tip pull test, switch operation test, spring obturator operation and needle puncture force test. All the results meet the acceptance criteria, they also demonstrate that the GTK Veress Needles meet the performance characteristics.

10. Statement of Substantial Equivalence

The Indications for Use and technological characteristics for GTK Veress Needles are same to the predicate devices (K172120). The non-clinical performance testing demonstrates that the proposed device is as safe and effective as the predicate devices. Therefore, the results show that it is Substantially Equivalent (SE) between

products and predicate devices.