DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 14, 2017

WickiMed (Huizhou) Medical Equipment Manufacturing Co.,Ltd.
Haobin Li
General Manager
Tang Jiao Wang Street, Lilin Town,
Zhongkai Hi-Tech Zone
Huizhou, Guangdong 516000
China

Re: K172120
Trade/Device Name: Veress Needle, models: WVN0112T, WVN0115T
Regulation Number: 21 CFR§ 884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: HIF, FHO
Dated: July 7, 2017
Received: July 13, 2017

Dear Haobin Li:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172120

Device Name

Veress Needle, models :WVN0112T,WVN0115T

Indications for Use *(Describe)*

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.

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 summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Type of submission :Traditional

The assigned 510(K) number is: K172120

The date the summary was prepared: September 11, 2017

1. Submitter information:

Manufacturer Name: WickiMed(Huizhou)Medical Equipment Manufacturing Co.,Ltd.

Address: TangJiao XingWang Street, LiLin Town, ZhongKai Hi-Tech Zone, HuiZhou,GuangDong, China.

Tel : 0086-0752-3860807

Fax : 0086-0752-3863017

Establishment Registration Number:3010601992

2. Contact person:

Haobin Li (General Manager)

WickiMed(Huizhou)Medical Equipment Manufacturing Co.,Ltd

TangJiao XingWang Street, LiLin Town, ZhongKai Hi-Tech Zone, HuiZhou,GuangDong, China.

Tel : 0086-0752-3860807

Fax : 0086-0752-3863017

E-mail: mac_lai@wickimed.com

3. Identification of the Device :

Trade Name: Veress Needle

Model: WVN0112T,WVN0115T

Common Name: Veress Needle

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Classification Name	Product Code	Regulation Number	Regulatory Class	Review Panel
Insufflator, Laparoscopic	HIF FHO	21CFR 884.1730	II	Obstetrics/Gynecology

4. Identification of the Predicative Device

Table 1: Predicative Device Information

Device Name	Common Name	Manufacturer	Classification and Code	Classification regulation	510(k) number
Unimicro Veress Needle	Veress Needle	Unimicro Medical Systems (ShenZhen) Co., Ltd.	Class II, HIF	21CFR 884.1730	K150068
			Class II, FHO	21CFR 876.1500	

There are no design-related recall records with Predicative Device K150068.

5. Intended Use and Indications for Use of the subject device

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.

6. Device Description

The Veress Needle is a sterile and single-use product. It incorporated a spring loaded blunt stylet mechanism similar to the needle. It is used to establish peritoneum prior to trocar and cannula insertion in laparoscopic procedures. The Veress Needle, available in 120 mm and 150 mm lengths, has applications in gynecological laparoscopy and other laparoscopic procedures.

7. Substantial Equivalence Determination

The Veress Needle submitted in this 510(k) file is substantially equivalent to the cleared Unimicro Veress Needle which is the subject of K150068.

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The comparison to the predicate device is provided below in Table 2.

Table 2 : Comparison to Predicate Device

Item	Predicate Device		Proposed Device	
Trade Name	Unimicro Veress Needle		Veress Needle	
510(K) Submitter	Unimicro Medical Systems (ShenZhen) Co.,Ltd.		WickiMed(Huizhou)Medical Equipment Manufacturing Co.,Ltd	
510(K) Number	K150068		-	
Classification regulation	21CFR 884.1730		21CFR 884.1730	
Classification and Product Code	Class II, HIF,FHO		ClassII, HIF,FHO	
Common name	Veress Needle		Veress Needle	
Intended Use	The Unimicro 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.		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.	
Components	Veress Needle Obturator		Veress Needle Obturator	
Models	MND 11200,MND 11500		WVN0112T,WVN0115T	
Length	120mm,150mm		120mm,150mm	
Sterilization	EO Sterilized		EO Sterilized	
Disposable	Yes		Yes	
Materials	Patient-Contacting Material	SUS 420	Patient-Contacting Material	SUS 304

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	（Outer tube inner tube ）		（Outer tube inner tube ）	
	Handle Material	ABS	Handle Material	PC
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	

The subject and predicate device have the same intended use. The subject and predicate device designs are nearly identical. Both are single-use devices and the lengths of the devices are identical. The differences in technological characteristics between the subject and predicate devices (i.e., different materials, and different needle inner diameter) do not raise different questions of safety and effectiveness.

8. Non-clinical Testing

A series of tests were performed to assess the safety and effectiveness of the Veress Needle. Biocompatibility tests were conducted in accordance with ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-7:2008, ISO 10993-10:2010, ISO 10993-11:2006, and ISO 10993-12:2012. The biocompatibility tests included Cytotoxicity, Sensitization, Intracutaneous reactivity, Acute systemic toxicity and Material-Mediated Pyrogenicity. Sterilization validation was performed per ISO 11135:2014.

The tests listed below evaluated the performance of the subject device.

- Tip Pull Test
- Switch Operation
- Spring Obturator Operation
- Needle Puncture Force Test

All the test results demonstrate the performance of Veress Needle meets the requirements of its pre-defined acceptance criteria and intended uses.

The results of the non-clinical testing demonstrate that the Veress Needle is as safe and effective as the predicate device.

9. Conclusion

Based on the results of the above described performance testing data, it can be concluded that Veress Needle is as safe and effective as the predicate device.