DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 12, 2016

Tianjin UWell Medical Device Manufacturing Co. Ltd.
Tao Fan
General Manager
A02, Plant B, No. 278, Hangkong Rd
Tianjin Free Trade Zone
Tianjin, CN 300308

Re: K162648
Trade/Device Name: U-Blade Veress Needle
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: Class II
Product Code: HIF, FHO
Dated: September 2, 2016
Received: September 22, 2016

Dear Tao Fan,

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 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 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,

For Division

Douglas Silverstein -S
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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)*
K162648

Device Name
U-Blade Veress Needle

Indications for Use *(Describe)*
The U-Blade 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
K162648

Submitter: Tianjin UWell Medical Device Manufacturing Co., Ltd.
A02, Plant B, No. 278, Hangkong Road, Tianjin Free Trade Zone (Airport Industrial Park), Tianjin, 300308

Contact: Mr. Fan, Tao General Manager
Phone: (86)18616806984
Email: fant01@uwellmed.com

Date Prepared: December 9, 2016

Device Trade Name: U-Blade Veress Needle

Device Common Name: Veress Needle

Classification Name: Laparoscopic insufflator

Class: II

Regulation Number: 884.1730

Panel: Obstetrical and Gynecological Devices

Product Code: HIF (Insufflator, Laparoscopic), FHO (Pneumoperitoneum needle)

1. Predicate Device:

Device	**Company**	**Product Code**	**510(k) Number**
Unimax Veress Needle	Unimax Medical Systems Inc	HIF FHO	K111441
The Predicate Device has not been subject to a design-related recall.			

2. Indications for Use:

The U-Blade 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.

3. Device Description:

The U-Blade Veress Needle is a slender, sharply-pointed metal tube designed to introduce or remove gas from the peritoneal cavity as a surgical/radiological procedural method. It is used for percutaneous insertion into the peritoneal cavity for the purpose of insufflation [e.g., with carbon dioxide (CO2)] to establish pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.

The device consists of an external stainless steel needle tube with a sharp point to puncture tissue. It is also equipped with an internal spring-loaded round-tipped obturator that extends from the tube when the device does not encounter resistance (i.e., when the cavity has been reached) to prevent damage to internal organs from the sharp point. The subject device also has a handle with a red indicator mark to verify when the spring-loaded obturator is retracted and a valve connector which connects to an insufflation pump.

As described in the following table, the U-Blade Veress Needle is available in 120mm and 150mm needle lengths and two types of handles with different shapes (U shape and Bugle).

Model Number	Length (mm)	Comments
UV120	120 mm	U shape handle
UV150	150 mm	U shape handle
BV120	120 mm	Bugle shape handle
BV150	150 mm	Bugle shape handle

This is a sterile and single-use device.

4. Non-Clinical Testing

A series of tests were performed to assess the safety and effectiveness of the U-Blade Veress Needle. These tests were conducted in accordance with ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010, ISO 10993-12:2012, ISO 11137-1:2006, and ISO 11137-2:2012.

Per ISO 10993-1:2009, the subject device is an external communicating device (tissue/bone/dentin) with limited contact duration (≤24 h); and therefore, the following biocompatibility tests were completed and demonstrated biocompatibility:

- Cytotoxicity Test (ISO 10993-5:2009)
- Intracutaneous Irritation Test (ISO 10993-10:2010)
- Skin Sensitization Test (the Guinea Pig maximization test) (ISO 10993-10:2010)

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

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

The performance test results demonstrate that the U-Blade Veress Needle meet its acceptance criteria.

Sterilization validation was conducted in accordance with ISO 11137-1:2006 and ISO 11137-2:2012.

Package integrity and functional performance testing were completed on the subject device following aging to support the proposed shelf life.

5. Substantial Equivalence Determination

The U-Blade Veress Needle and the predicate device have the same intended use but different technological characteristics. The differences in technological characteristics between the devices do not raise different questions of safety or effectiveness.

The comparison to predicate device is described in the table below.

Comparison to Predicate Device

	Proposed Device (U-Blade Veress Needle)	**Predicate Device (Unimax Veress Needle, K111441)**
Trade Name	U-Blade Veress Needle	Unimax Veress Needle
510(k) Submitter	Tianjin UWell Medical Device Manufacturing Co., Ltd	Unimax Medical Systems Inc.
510(k) Number	K162648	K111441
Common Name	Veress Needle	Veress Needle
Classification	CFR 884.1730	21 CFR 884.1730
Classification and Product Code	Class II, HIF, FHO	Class II, HIF, FHO
Device Classification Name	Laparoscopic insufflator	Laparoscopic insufflator
Models	UV120/150, BV 120/150	xVN Series

Comprised Elements	Needle tube, Inner Blunder stylet, Handle, and Valve connector	Needle tube, Inner Blunder stylet, Handle, and Valve connector
Materials:	PC resin, SUS 304/316	PC resin, SUS 304, Acrylonitrile styrene
Dimension	Length:	Length:
	120-150 mm	120-150 mm
Indications for Use	Intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish pneumoperitoneum prior to the	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.	placement of trocars during laparoscopic procedures.
Sterilization method	Gamma sterilization	EO sterilization
Disposable for Single Use	Yes	Yes

6. Conclusion

Based upon the performance tests, it can be concluded that the UWell Veress Needle is as safe and effective as the predicate device. Therefore, UWell Veress Needle is substantially equivalent to the Unimax Veress Needle.