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

January 11, 2017

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

Re: K162387
Trade/Device Name: U-IGNITE Bladeless Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 10, 2016
Received: August 25, 2016

Dear Mr. 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 801and Part 809), 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 Post Market 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,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K162387

Device Name
U-IGNITE Bladeless Trocar

Indications for Use *(Describe)*
The U-IGNITE Bladeless Trocar has applications in endoscopic procedures to provide a port 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
K162387

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

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

Date Prepared: Jan., 4, 2017

Device Trade Name: U-IGNITE Bladeless Trocar

Device Common Name: Disposable Surgical Trocar / Cannula

Classification Name: Laparoscope, General & Plastic Surgery

Class: II

Regulation Number: 876.1500

Panel: General & Plastic Surgery

Product Code: GCJ

Primary Predicate Device:

Device	Company	Product Code	510(k) Number
ENDOPATH XCEL Bladeless Trocar with OPTI VIEW Technology	Ethicon Endo-Surgery, LLC	GCJ	K122511

Reference Device:

Device	Company	Product Code	510(k) Number
Unimicro Trocar Kit, models: Auto-Locking	Unimicro Medical Systems (ShenZhen) Company,	GCJ	K141594

3. Indications for Use:

The U-IGNITE Bladeless Trocar has applications in endoscopic procedures to provide a port of entry for endoscopic instruments.

3. Product Description:

It is a rigid hand-held surgical instrument with a rounded conical point used to manually puncture a bodily entry point to assist in the location and positioning of gently part the surrounding soft tissue. The trocar assembly punctures the muscle and tissue layers in the body. The trocar assembly's obturator is removed leaving the cannula to provide a port through which laparoscopes and other laparoscopic instruments can be introduced. The cannula sealing system shall be able to maintain pneumoperitoneum.

The U-IGNITE Bladeless Trocar is a sterile single patient use instrument consisting of a radiolucent sleeve and obturator in various sizes diameter. The obturator contains a clear, taped optical element. The obturator accommodate an appropriate sized 0 degree endoscope and provide visibility of individual tissue layers during insertion. Basic type do not have the optical element for its obturator.

In addition, the U-IGNITE Bladeless Trocar with Endo-assistant part is a design enhancement that reduces the incidence of trocar-induced endoscope lens smudging during endoscope insertion. Endoscope smudging occurs when bodily fluids and debris smear across the endoscope lens during a laparoscopic procedure. Trocar-induced smudging occurs when these bodily fluids and debris are deposited within the trocar's seal system when an endoscope or instrument has been exchanged through the trocar.

The trocar sleeves for the 12 mm devices contain two seals, an outer integrated removable self-adjusting seal that accommodates instruments ranging from 5mm to 12 mm in diameter where indicated and an internal seal. Together, these two seals minimize gas leakage when instruments are inserted or withdraw through the trocar. The 5 mm trocar sleeve does not contain an integrated removable outer seal and accommodates only 5 mm instruments.

A stopcock valve is compatible with standard luer lock fitting and provides attachment for gas insufflation and desufflation. The stopcock is in the closed position when it is parallel to the sleeve.
This is an irradiation sterilized single use disposable device to avoid cross infection.

Product Specification

Trocar			
Product Code	Allow Size(mm)	Length (mm)	Comments
IG5ST	5	75	Without Endo. Assistant part
IG5LT	5	100	Without Endo. Assistant part
SIG5ST	5	75	With Endo. Assistant part
SIG5LT	5	100	With Endo. Assistant part
BIG5ST	5	75	Basic Type
BIG5LT	5	100	Basic Type
BIG8LT	8	100	Basic Type
IG10LT	10	100	Without Endo. Assistant part
IG10XT	10	150	Without Endo. Assistant part
SIG10LT	10	100	With Endo. Assistant part
SIG10XT	10	150	With Endo. Assistant part
IG12ST	12	75	Without Endo. Assistant part
IG12LT	12	100	Without Endo. Assistant part
SIG12ST	12	75	With Endo. Assistant part
SIG12LT	12	100	With Endo. Assistant part
BIG12ST	12	75	Basic Type
BIG12LT	12	100	Basic Type

Basic type is a simplified version of normal type without Endo-Assistant part.

4. Non-Clinical Testing

A series of safety tests were performed to access the safety and effectiveness of the U-IGNITE Bladeless trocar. The safety tests were conducted in accordance with ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-12, and ISO 11137-1/-2. The performance testing conducted on subject device and predicate device are listed below:

- Obturator & Cannula Compatibility
- Insertion &Cannula Stability
- Air Leakage as a whole device
- Trocar System Puncture Performance (animal simulation test)
- Trocar sleeve retention force (animal simulation test)
- Air Leakage with obturator withdrawed
- Endoscope Visualization Image Quality
- Endo-Assistant Part Liquid Absorbing Performance

All the test results demonstrate U-IGNITE Bladeless trocar meet the requirements of its pre-defined acceptance criteria and intended uses.

5. Clinical Data Evaluation：

Based on this literature review no new risks that have not already been identified in the instructions for use or the previously reviewed literature have been noted.

After search from websites cited, post manufacturing experience and data, no clinical incident is reported that is the cause of the trocar device itself.

Identified hazards, such as the occurrence of incisional hernias and injuries to internal viscera and vessels are hazards that are ordinarily associated with operative procedures in the anatomical regions examined regardless of method.

These post-manufacturing experience/ risks are considered & evaluated periodically in our own risk analysis management system, e.g. the Instruction for Use updating based on the literature review result.

Summary of the referred literature and expert opinions that shows that the method is safe and that the device fulfils its intended purpose and clinical performance.

6. Substantial Equivalence Determination

The indications for use and technology characteristics of the proposed U-IGNITE Bladeless Trocar, and the substantial equivalence to the predicate devices have been demonstrated via data collected in design verifications. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its indications for use. And the differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

The comparison to predicate devices as below table.

Comparison to Predicate Device and Reference Device

Item	Proposed Device (U-IGNITE Bladeless Trocar)	Primary Predicate Device (ENDOPATH XCEL Bladeless Trocar with OPTI VIEW Technology)	Reference Device (Unimicro Trocar Kit, models: Auto-Locking Trocar, Hasson)
Models	Bladeless without Endo-Assistant Part (BIG & IG models)	Bladeless	Bladeless
	Bladeless with Endo-Assistant Part (SIG model)	Bladeless with OPTIVIEW™ Technology	/
	/	/	Auto-Locking
	/	Dilating Tip	/
	/	Blunt Tip (Hasson)	Hasson
Comprised Elements	Cannula sleeve, Obturator	Cannula sleeve, Obturator	Cannula sleeve, Obturator
Dimension	Diameter:	Diameter:	Diameter:
	5-12 mm	5-12 mm	5-12 mm
	Length:	Length:	Length:
	75-150 mm	75-150 mm	70-120 mm
Classification	21 CFR 876.1500	21 CFR 876.1500	21 CFR 876.1500
Classification and Code	Class II, GCJ	Class II, GCJ	Class II, GCJ
Device Classification Name	Laparoscope, General & Plastic Surgery	Laparoscope, General & Plastic Surgery	Laparoscope, General & Plastic Surgery
Indications for Use	applications in endoscopic procedures to provide a port of entry for endoscopic instruments	Applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic Instruments. The trocar may be used with or without visualization for primary and secondary insertions.	Application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments.
Sterilization	Gamma sterilization	Gamma sterilization	EO sterilization

Safety standards	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-12 ISO 11137-1	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-12 ISO 11137-1	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-7 ISO 10993-12 ISO 11135
Performance Standards	Not Applicable	Not Applicable	Not Applicable
Performance Testing Item	Obturator & Cannula Compatibility	Obturator & Cannula Compatibility	Obturator & Cannula Compatibility
	Insertion &Cannula Stability	Insertion &Cannula Stability	Insertion &Cannula Stability
	Trocar System Puncture Performance	Trocar System Puncture Performance	Trocar System Puncture Performance
	Trocar sleeve retention force	Trocar sleeve retention force	Trocar sleeve retention force
	Air Leakage as a whole device	Air Leakage as a whole device	Air Leakage as a whole device
	Air Leakage with obturator withdrawed	Air Leakage with obturator withdrawed	Air Leakage with obturator withdrawed
	Endoscope Visualization Quality	Endoscope Visualization Quality	Not Applicable
	Endo-Assistant Part Liquid Absorbing Performance	Endo-Assistant Part Liquid Absorbing Performance	Not Applicable
Comparison Summary	The subject device has the same or simpler intended use comparing to predicate device and reference device. The subject device has same design, construction, and operation principle comparing to predicate device, K122511 and reference device K141594. For both subject device and predicate & reference device, all materials and final assembled product used can comply with the biocompatibility international standard ISO 10993-1, with the evidence from Third Party report. And the test results show the materials used and final product safe biologically. The technology and performance specification of our product (type SIG series and IG series), Bladeless Trocar with Endo-assistant part, are same in Essential Components, physical and general safety feature comparing to the primary predicate device, K122511 from ENDOPATH XCEL Bladeless Trocar with OPTIVIEW Technology, and Bladeless XCEL. Compare to the reference device specified in K141594, our product (type IG, and type BIG series) and the reference device are same in physical and general safety features based on bench test results. The subject device utilizes the same sterilization method, Gamma irradiation sterilization, as what used in primary predicate device, K122511. This sterilization method is safer than EO sterilization method used in K141594. With the same / smaller intended use scope & same principle of operation, and complying with the similar bench tests, the proposed device, Tianjin UWell Medical Device Manufacturing Co. Ltd., performs in same manner to the predicate device, ENDOPATH XCEL Bladeless Trocar with OPTI VIEW Technology, and reference device,		

	Unimicro Trocar Kit, with respect to the following characteristics: ● Design ● Operation principle ● Constructed materials, ● Performance characteristics ● Perceived safety of the device Any minor structure, material, dimensional or labeling differences between the predicate & reference device and the subject device do not pose risk to their performance and usage.

7. Conclusion

After analyzing bench tests, safety testing data, it can be concluded that: U-IGNITE Bladeless Trocar is as safe and effective as the predicate device and reference device.