October 27, 2017

WickiMed (Huizhou) Medical Equipment Manufacturing Co.,Ltd.
Haobin Li
General Manager
Tang Jiao XingWang Street, LiLin Town
Zhongkai Hi-Tech Zone
HuiZhou, GuangDong, China 516000

Re: K172038/S001
Trade/Device Name:Trocar, Model: Auto-Locking Trocar, Bladeless Trocar, Visible Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 21, 2017
Received: September 26, 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,

Jennifer R. Stevenson -S3

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: June 30, 2020
See *PRA Statement below.*

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

K172038

**Device Name**
Trocar, models: Auto-Locking Trocar, Bladeless Trocar, Visible Trocar

**Indications for Use** *(Describe)*
The Trocar, Model: Auto-Locking Trocar, Bladeless Trocar and Visible Trocar has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments.

Type of Use *(Select* one *or both,* as *applicable)*

[X] 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 Paperwor1< Reduction Act of 1995.

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

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WickiMed (Huizhou) Medical Equipment Manufacturing Co., Ltd.

# 510(K) SUMMARY

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

Type of submission: Traditional

The assigned 510(K) number is: K172038

The date the summary was prepared: September 20 ,2017

## 1. Submitter information:

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

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Tel : 0086-0752-3860807

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Establishment Registration Number:3010601992

## 2. Contact person:

Haobin Li (General Manager)

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## 3. Identification of the Device

**Trade Name:** Trocar

**Model:** Auto-Locking Trocar, Bladeless Trocar, Visible Trocar

**Common Name:** Disposable Surgical Trocar /Cannula

**Classification Name:** Laparoscope, General & Plastic Surgery

**Regulation Number:** 876.1500

**Device Classification:** II

**Product Code:** GCJ

## 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 Trocar Kit | Disposable Surgical Trocar /Cannula | Unimicro Medical Systems (ShenZhen) Co., Ltd. | Class Ⅱ, GCJ | 21CFR 876.1500 | K141594 |
| Unimax Trocar System | Disposable Surgical Trocar /Cannula | Unimax Medical Systems Inc. | Class Ⅱ, GCJ | 21CFR 876.1500 | K112358 |

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

The Trocar Models: Auto-Locking Trocar, Bladeless Trocar and Visible Trocar, has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments.

## 6. Device Description

The Auto-Locking Trocar has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments. The Auto-Locking Trocar is available in three kinds of diameter sizes: 5mm, 10mm and 12mm. The cannula assembly has a universal seal, a valve, and a stopcock. This device has a bladed tip with an internal shield, which is designed to cover the cutting edges once the body cavity has been entered. Auto-Locking Trocar 10 mm can accept 4 mm to 11 mm sized instruments with its built-in universal seal without the use of a converter. Auto-Locking Trocar 12 mm can accept 4 mm to 13 mm sized instruments with its built-in universal seal without the use of a converter.

The Bladeless Trocar has application in a variety of endoscopic procedures to provide a

port of entry for endoscopic instruments. The Bladeless Trocar is available from 5-12mm: The cannula assembly (10mm to 12mm type) has a universal seal, a valve, and a stopcock. The cannula assembly (5mm type) has a stopcock.

The Visible Trocar has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments. This device has a blunt tip,, which is designed for open Laparoscopy. The visible trocar is available in three sizes: 5mm, 10mm and 12mm. This device allows direct visualization of the abdominal wall layers when the trocar is traversed, which offers a safe and rapid option of primary trocar. The cannula assembly has a universal seal, a valve and a stopcock.

**7. Substantial Equivalence Determination**

The Trocar submitted in this 510(k) file is substantially equivalent to the cleared Unimicro Trocar Kit (K141594) and Unimax Trocar System( K112358).

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

**Table 2 : Comparison to Predicate Device**

| **Item** | **Proposed Device** Trocar | **Predicate Device** Unimicro Trocar Kit K141594 | **Predicate Device** Unimax Trocar System K112358 |
|---|---|---|---|
| Classification regulation | 21 CFR 876.1500 | 21 CFR 876.1500 | 21 CFR 876.1500 |
| Classification and Code | Class II , GCJ | Class Ⅱ , GCJ | Class Ⅱ , GCJ |
| Common Name | Disposable Surgical Trocar /Cannula | Disposable Surgical Trocar /Cannula | Disposable Surgical Trocar /Cannula |
| Indications for Use | Applicate in a variety of endoscopic procedures to provide a port of entry for endoscopic | Applicate in a variety of endoscopic procedures to provide a port of entry for endoscopic | Applicate in a variety of endoscopic procedures to provide a port of entry for endoscopic |

| | | | | |
|---|---|---|---|---|
| | | instruments. | instruments. | instruments. |
| Principles of operation | | Trocar inserted into the skin incision, and punctured into the abdominal cavity. Removed the puncture cone and made a surgical channel. | Trocar inserted into the skin incision, and punctured into the abdominal cavity. Removed the puncture cone and made a surgical channel. | Trocar inserted into the skin incision, and punctured into the abdominal cavity. Removed the puncture cone and made a surgical channel. |
| Model | | Auto-Locking Trocar | Auto-Locking Trocar | / |
| | | Bladeless Trocar | Bladeless Trocar | / |
| | | Visible Trocar | / | Visible Trocar |
| Mainly Structure | | Cannula,(blade), universal seal, valve, stopcock | Cannula , (blade), universal seal, valve, stopcock | Cannula, universal seal, valve, stopcock |
| Specification | | Diameter :5-12mm | Diameter :5-12mm | Diameter :3-15mm |
| | | Length :100mm | Length :70-120mm | Length :65-150mm |
| Technology Characteristic | | The built-in universal seal design for Trocar 10 mm and 12mm and without the use of a converter. | The built-in universal seal design for Trocar 10 mm and 12mm and without the use of a converter. | The built-in universal seal design for Trocar 10 mm and 12mm and without the use of a converter. |
| Patient-contacting structure | ATR | Blade, Cutting head ,Cannula | Blade, Cutting head ,Cannula | / |
| | BTR | Cutting head , Cannula | Cutting head ,Cannula | / |
| | VTR | Cutting head , Cannula | / | Cutting head ,Cannula |

| | | | | |
|---|---|---|---|---|
| Patient-contacting Materials | ATR | Stainless Steel, PC,ABS | Stainless Steel, PC,ABS | / |
| | BTR | PC,ABS | PC,ABS | / |
| | VTR | PC | / | PC |
| Safety standards | | ISO 10993-1<br>ISO 10993-5<br>ISO 10993-7<br>ISO 10993-10<br>ISO 10993-11<br>ISO 10993-12<br>ISO 11135 | ISO 10993-1<br>ISO 10993-5<br>ISO 10993-7<br>ISO 10993-10<br>ISO 10993-12<br>ISO 11135-1 | ISO 10993-1<br>ISO 10993-5<br>ISO 10993-7<br>ISO 10993-10<br>ISO 10993-12<br>ISO 11135-1 |
| Performance testing items | | Obturator compatibility | Obturator compatibility | Obturator compatibility |
| | | Insertion & cannula stability | Insertion & cannula stability | Insertion & cannula stability |
| | | Air leakage | Air leakage | Air leakage |
| | | Trocar Insertion/ Removal force | / | / |
| Sterilization | | EO Sterilized | EO Sterilized | EO Sterilized |

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 structure and technology characteristic are identical. The differences in specification between the subject and predicate devices 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 Trocar. 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.

The performance testing conducted on subject device is listed below:

- Obturator Compatibility
- Insertion & Cannula Stability
- Air Leakage
- Trocar Insertion/ Removal force

All the test results demonstrate Trocar meet the requirements of its pre-defined acceptance criteria and intended uses.

**9. Conclusion**

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