November 17, 2020

Wuxi Shukang Medical Appliance Co., Ltd.
Xiaoqing Yuan
Sales Manager
No.83, Haitang West Road, Zhakou, Heqiao Town
Yixing, Jiangsu 214216
China

Re: K202931
Trade/Device Name: Disposable Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 10, 2020
Received: September 29, 2020

Dear Xiaoqing Yuan:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K202931

Device Name
Disposable Trocar

Indications for Use *(Describe)*
The Disposable 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)

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

1. Contact Information

1.1. Applicant

Applicant Name: Wuxi Shukang Medical Appliance Co., Ltd.
Address: No. 83, Haitang West Road, Zhakou Heqiao Town, Yixing, Jiangsu, 214216 China
Contact Person: Xiaoqing Yuan
Title: Sales Manager
Telephone: 0086-510-87881818
E-mail: info@surkonmed.com

1.2. Designated Submission Correspondent

Company: Sinow Medical AS
Address: Vestre Fantoftåsen 44, 5072, Bergen, Norway
Contact Person: Huifang Zhao
Telephone: +86 13961151430
Email: zhao@bergemed.com

2. Device information

Trade Name: Disposable Trocar
Common Name: Disposable Surgical Trocar
Classification: II
Product Code: GCJ
Regulation: 21 CFR 876.1500

3. Legally Marketed Primary Predicate Device

Product name: U-IGNITE Bladeless Trocar
510K Number: K162387
Product Code: GCJ
Manufacture: Tianjin UWell Medical Device Manufacturing Co., Ltd.

4. Device Description

The disposable Trocar has application 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.

The Disposable trocar is mainly composed of Obturator with bladeless tip, Outer Seal Release Lever, Trocar Stability Sleeve, Obturator Locking Button, etc.

5. Indication for use:

The Disposable Trocar has applications in endoscopic procedures to provide a port of entry for endoscopic instruments.

6. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	**Proposed Device**	**Primary Predicate Device** U-IGNITE Bladeless Trocar K162387	**Reference Device** Unimax Trocar System K112358
Product Code	GCJ	GCJ	GCJ
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	21 CFR 876.1500
Indication for use	The Disposable Trocar has applications in endoscopic procedures to provide a port of entry for endoscopic instruments.	The U-IGNITE Bladeless Trocar has applications in endoscopic procedures to provide a port of entry for endoscopic instruments.	Applicate in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments.
Models	SHTA， SHTB， SHTC ,SHTD and SHTE which is bladeless without Endo-Assistant Part.	Bladeless without Endo-Assistant Part (BIG & IG models)	Bladeless Trocar
Dimension	Diameter: 3-15mm	Diameter: 5-12mm	Diameter: 3-15mm
	Length:80-150mm	Length:75-150 mm	Length:65-150mm
Principles of operation	During the operation, the trocar sleeve and the obturator are used together. The surgeon uses the obturator to expand the incision of the abdomen and penetrates the trocar sleeve through the abdominal surface of the human body into the abdominal cavity, thereby delivering gas to the abdominal cavity and establishing a path of entry for	During the operation, the trocar sleeve and the obturator are used together. The surgeon uses the obturator to expand the incision of the abdomen and penetrates the trocar sleeve through the abdominal surface of the human body into the abdominal cavity, thereby delivering gas to the abdominal cavity and establishing a path of entry for	/

	endoscopic instruments.	endoscopic instruments.	
Main Components	Obturator, Sleeve	Cannula Sleeve; Obturator	Cannula Tip of obturator
Patient Contacting Structure	Obturator Trocar Sleeve	Obturator Cannula Sleeve	/
Patient Contacting Material	PC, ABS	PC， ABS	/
Sterilization	Gamma sterilization	Gamma sterilization	EO Sterilized

7. Non-Clinical Test conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

(1) Bench Performance test:
Performance test was conducted to demonstrate the proposed Disposable Trocar is substantially equivalent to the predicate devices. The performance tests include the following tests:

- Visual Inspection
- Insertion and Removal Force using obturator
- Leakage
- In Vitro Penetration Force
- In Vitro Retention Force

(2) Biocompatibility evaluation and test
Biocompatibility evaluation conducted in accordance with the FDA's 2016 guidance and ISO10993-1:2018 supports that the subject devices are biocompatible. The biocompatibility test includes the following tests:
In Vitro Cytotoxicity Test（ISO 10993-5: 2009）
Skin Sensitization Test（ISO 10993-10:2010）
Intracutaneous reactivity Test（ISO 10993-10:2010）
Acute Systemic Toxicity（ISO 10993-11:2017）
Pyrogen Test（ISO 10993-11:2017）

(3) Sterilization and Shelf Life Accelerated Aging Test
Aging test report for product performance:
Validation report for the sterilization by Gamma irradiation process (ISO 11737-2:2019)
Test of Sterile Barrier System 3 Years Shelf Life.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.