September 26, 2019

Changzhou Xin Neng Yuan Medical Stapler Co., Ltd.
℅ Ms. Diana Hong
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 China

Re: K190029
Trade/Device Name: Disposable Bladeless Trocar, Disposable Optical Trocar, Disposable Blunt-Tip Trocar, Disposable Spiral Trocar, and Disposable Bladed Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 26, 2019
Received: August 28, 2019

Dear Ms. Hong:

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)*
K190029

Device Name
Disposable Bladeless Trocar, Disposable Optical Trocar and Disposable Bladed Trocar

Indications for Use *(Describe)*
The devices, Disposable Bladeless Trocar, Disposable Optical Trocar and Disposable Bladed Trocar, have applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path 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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K190029

1. Date of Preparation: 09/23/2019

2. Sponsor Identification

**Changzhou Xin Neng Yuan Medical Stapler Co., Ltd.**
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3. Designated Submission Contact Persons

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)
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4. Identification of Proposed Device

Device Trade Name: Disposable Bladeless Trocar, Disposable Optical Trocar and Disposable Bladed Trocar
Device Common Name: Disposable Trocar/Cannula

Regulatory Information:
Classification Name: Laparoscope, General & Plastic Surgery;
Classification: II;
Product Code: GCJ;
Regulation Number: 876.1500;
Review Panel: General & Plastic Surgery;

Intended Use Statement:

The proposed devices, Disposable Bladeless Trocar, Disposable Optical Trocar and Disposable Bladed Trocar, have applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments.

Device Description

The proposed devices, Disposable Bladeless Trocar, Disposable Optical Trocar and Disposable Bladed Trocar, are basic equipment used during laparoscopic surgical, which consist of Puncture Needle, Puncture Sleeve, Injection Valve, Cap and Safety lock. They are available in multiple configurations, including bladed type, bladeless type and optical type. In order to obtain access to the surgical site during laparoscopic surgery, the Puncture Needle is introduced into Puncture Sleeve to accomplish cannula penetration of the abdominal wall. The sleeve is connected to the Injection Valve at its proximal end and once the abdominal/thoracic wall is punctured, the puncture needle is removed. The sleeve acts as a channel for the introduction of the endoscopes and instruments. Generically, puncture needle and sleeve are available in a range of lengths and diameters to accommodate different sizes surgical instrument

5. Identification of Predicate Devices

Predicate Device 1

510(k) Number: K122511

Product Name: ENDOPATH® XCEL® Bladeless Trocar with OPTIVIEW™ Technology

Predicate Device 2

510(k) Number: K062362

Product Name: Autosuture Modified Versaport Trocar with Fixation Sleeve

6. Non-Clinical Test Conclusion

Following non clinical tests were conducted. Performance Tests, both bench and in vivo study, were performed on both the proposed devices and predicate devices. The results demonstrated that the performances of the proposed device are substantial equivalent to those of the predicate device. Results of biocompatibility, sterility and packaging tests demonstrated that the proposed devices met their specifications and requirements.

Performance Tests - Bench

- Instrument Insertion and Removal Force Test;
- Leak Resistance Test;
- Snap Feature Retention Force Test.

Performance Tests – in vivo Study

An in vivo study was conducted on porcine model to evaluate the penetration force, fixation force and visualization performance (for optical type only), in addition, tip integrity was also evaluated after each insertion.

Biocompatibility

- Cytotoxicity per ISO 10993-5:2009 Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro Cytotoxicity;
- Irritation and Sensitization per ISO 10993-10:2010 Biological Evaluation of Medical Devices-Part

10: Tests for Irritation and Skin Sensitization;

- Pyrogen Study per ISO 10993-11:2006 Biological Evaluation of Medical Devices-Part 11: Tests for Systemic Toxicity;

Sterility and Packaging

- ISO 10993-7:2008 Biological Evaluation Of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals;
- ASTM F88/F88M-15 Standard test method for seal strength of flexible barrier materials;
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration;
- USP <85> Endotoxin Limit Test

7. Clinical Testing

No clinical study was done.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison for Disposable Bladeless Trocar and Disposable Optical Trocar with predicate device 1 (k122511)

| ITEM | Proposed Device<br>Disposable Bladeless Trocar | Proposed Device<br>Disposable Optical Trocar | Predicate Device 1<br>K122511 |
|---|---|---|---|
| Classification | II | II | II |
| Regulation No. | 876.1500 | 876.1500 | 876.1500 |
| Product Code | GCJ | GCJ | GCJ |
| Intended Use | The device has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. | The device has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. | The ENDOPATH® XCEL® Bladeless Trocar has 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. |
| Configuration | Puncture Needle<br>Puncture Sleeve<br>Reducer Cap | Puncture Needle<br>Puncture Sleeve<br>Reducer Cap | Puncture Needle<br>Puncture Sleeve<br>Reducer Cap |
| Single Use | Single Use | Single Use | Single Use |
| Operation Mode | Manually | Manually | Manually |
| Accessory | Puncture sleeve, reducer cap | Puncture sleeve, reducer cap | No accessory |
| Safety features | No safety feature | No safety feature | No safety feature |

| | | | |
|---|---|---|---|
| Label/Labeling | Comply with 21, CFR Section 801 | Comply with 21, CFR Section 801 | Comply with 21, CFR Section 801 |
| Shaft Diameter | Available in 3, 5, 8, 10, 12, and 15mm | Available in 5, 8, 10 and 12mm | Available in 5 and 12mm |
| Shaft Length | Available in 75 and 100mm | Available in 75 and 100mm | Available in 75, 100 and 150mm |
| Material | ABS, PC, PE, Colorant, Rubber | ABS, Stainless Steel, PC, PE, Rubber, Colorant | Unknown |
| Trocar Width | 52.4mm, 61.4m | 52.4mm, 61.4mm | Unknown |
| Total Length | 158mm, 184mm, 172mm, 197mm | 158mm, 172mm, 184mm, 197mm | Unknown |
| Needle Tip Shape | Fin | Fin | Fin |
| Sterilization | EO sterilized | EO sterilized | Irradiation sterilized |
| SAL | $10^{-6}$ | $10^{-6}$ | $10^{-6}$ |
| Endotoxin Limit | 20 EU per device | 20 EU per device | 20 EU per device |
| Shelf life | 2 years | 2 years | 3 years |
| Packaging method | Sealing method | Sealing method | Sealing method |
| Cytotoxicity | No cytotoxicity | No cytotoxicity | Comply with ISO 10993 |
| Skin Irritation | No irritation | No irritation | |
| Sensitization | No sensitization | No sensitization | |
| Pyrogen | No pyrogen | No pyrogen | |

Table 2 Comparison for Disposable Bladed Trocar with predicate device 2 (K062326)

| ITEM | Proposed Device<br>Disposable Bladed Trocar | Predicate Device 2<br>K062326 |
|---|---|---|
| Classification | II | II |
| Regulation No. | 876.1500 | 876.1500 |
| Product Code | GCJ | GCJ |
| Intended Use | The device has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. | The autosuture™ Modified VERSAPORT™ trocar with fixation sleeve is intended for use in a variety of gynecologic, general, thoracic and urologic endoscopic procedures to create and maintain a port of entry |
| Configuration | Puncture Knife<br>Puncture Sleeve<br>Reducer Cap<br>Puncture Needle | Puncture Knife<br>Puncture Sleeve<br>Reducer Cap<br>Puncture Needle |
| Single Use | Single Use | Single Use |
| Operation Mode | Manually | Manually |
| Accessory | Puncture sleeve, reducer cap | No accessory |
| Safety features | Yes | Yes |

| | | |
|---|---|---|
| Label/Labeling | Comply with 21, CFR Section 801 | Comply with 21, CFR Section 801 |
| Shaft Diameter | Available in 5, 8, 10 and 12mm | Available in 5, 11 and 12mm |
| Shaft Length | Available in 75 and 100mm | Short, regular, long |
| Material | ABS, Stainless Steel, PC, PE, Rubber, Colorant | Unknown |
| Trocar Width | 52.4mm, 61.4mm | Unknown |
| Total Length | 158mm, 172mm, 184mm, 198mm | Unknown |
| Needle Tip Shape | Blunt | Blunt |
| Sterilization | EO sterilized | EO sterilized |
| SAL | $10^{-6}$ | $10^{-6}$ |
| Endotoxin Limit | 20 EU per device | 20 EU per device |
| Shelf life | 2 years | 3 years |
| Packaging method | Sealing method | Sealing method |
| Cytotoxicity | No cytotoxicity | Comply with ISO 10993 |
| Skin Irritation | No irritation | |
| Sensitization | No sensitization | |
| Pyrogen | No pyrogen | |

Any technical differences have been justified, both scientifically and using performance testing. These do not affect the safety or effectiveness of the proposed device.

**CONCLUSION**

Based on testing and comparison with the predicate device, the proposed devices shows no adverse indications or results. It is our determination that the proposed device is safe, effective and performs within its design specifications and is substantially equivalent to the predicate devices.

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