March 22, 2023

Taiwan Surgical Corporation
Ken Chen
Project Director
3F., No. 12, Sec. 2
Sheng Yi Rd.
Zhubei City, Hsinchu County 30261
Taiwan

Re: K223593
Trade/Device Name: Inno-Port Disposable Bladeless Trocar, Inno-Port Disposable Optical Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: November 29, 2022
Received: December 1, 2022

Dear Ken Chen:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.03.22 15:37:30 -04'00'

Mark Trumbore, 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K223593

Device Name
Inno-Port Disposable Bladeless Trocar and Inno-Port Disposable Optical Trocar

Indications for Use *(Describe)*
The Inno-Port Disposable Bladeless Trocars are intended for use in a variety of gynecologic, general thoracic and urologic endoscopic procedures to create and maintain a port of entry.

The Inno-Port Disposable Optical Trocars are intended for use in a variety of gynecologic, general thoracic and urologic endoscopic procedures to create and maintain a port of entry. The trocar may be used with or without visualization for primary and secondary insertions.

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.***

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# 510(k) Summary

The Assigned 510(k) Number: K223593

Date Prepared: 11/02/2022

This 510(k) summary of safety and effectiveness information is submitted as part of the Premarket Notification in compliance with requirements of CFR Part 807, Subpart E and Section 807.92

## 1 SUBMITTER:


| | |
|---|---|
| Submitter: | TAIWAN SURGICAL CORPORATION |
| Mailing Address: | 3F., No.12, Sec.2, ShengYi Rd., Zhubei City, Hsinchu County 302, Taiwan |
| Phone Number: | +886-3-6588129 |
| Fax Number: | +886-3-6588355 |

| | |
|---|---|
| Contact Person: | Ken Chen |
| Title: | Project Director |
| Address: | 3F., No.12, Sec.2, ShengYi Rd., Zhubei City, Hsinchu County 302, Taiwan |
| Date of submission: | 03/20/2023 |
| Email: | ra@twsc.com.tw |
| Phone Number: | +886-3-6588129 ext. 100 |
| Fax Number: | +886-3-3588355 |


## 2 DEVICE

| | |
|---|---|
| Trade Name: | Inno-Port Disposable Bladeless Trocar and Inno-Port Disposable Optical Trocar |
| Common Name: | Surgical Trocar |
| Panel Number: | 78 Gastroenterology and Urology |
| Classification Name: | 21 CFR Part 876.1500 Endoscope and accessories |
| Classification Product Code: | GCJ |
| Device Class: | II |

## 3 PREDICATE DEVICE

VeraPort™ V2 Bladeless Optical Trocar (11&1 2mm: K130435, 5 mm: K112349)

VersaOne™ Bladeless Trocar (K151548)

## 4 DEVICE DESCRIPTION

**Inno-Port Disposable Bladeless Trocar**

The Inno-Port Disposable Bladeless Trocars are available in the following configurations:

| Series | Model No. | Product Description and Specification |
|---|---|---|
| 5 mm series | DT501-7B | Disposable Trocar, 5mm, Length 70mm, Bladeless (Obturator*1, Cannula*1) |
| | DT501-XB | Disposable Trocar, 5mm, Length 100mm, Bladeless (Obturator*1, Cannula*1) |
| | DT501-7L | Disposable Trocar, 5mm, Length 70mm, Bladeless (Obturator*1, Cannula*2) |
| | DT501-XL | Disposable Trocar, 5mm, Length 100mm, Bladeless (Obturator*1, Cannula*2) |
| | DT501-71 | Disposable Trocar, 5mm, Length 70mm (Cannula*1) |
| | DT501-X1 | Disposable Trocar, 5mm, Length 100mm (Cannula*1) |
| 5-11 mm series | DTW01-XB | Disposable Trocar, 5-11mm, Length 100mm, Bladeless (Obturator*1, Cannula*1) |
| | DTW01-SB | Disposable Trocar, 5-11mm, Length 150mm, Bladeless (Obturator*1, Cannula*1) |
| | DTW01-XL | Disposable Trocar, 5-11mm, Length 100mm, Bladeless (Obturator*1, Cannula*2) |
| | DTW01-SL | Disposable Trocar, 5-11mm, Length 150mm, Bladeless (Obturator*1, Cannula*2) |
| | DTW01-X1 | Disposable Trocar, 5-11mm, Length 100mm (Cannula*1) |
| | DTW01-S1 | Disposable Trocar, 5-11mm, Length 150mm (Cannula*1) |
| 5-12 mm series | DTY01-XB | Disposable Trocar, 5-12mm, Length 100mm, Bladeless (Obturator*1, Cannula*1) |
| | DTY01-SB | Disposable Trocar, 5-12mm, Length 150mm, Bladeless (Obturator*1, Cannula*1) |
| | DTY01-XL | Disposable Trocar, 5-12mm, Length 100mm, Bladeless (Obturator*1, Cannula*2) |
| | DTY01-SL | Disposable Trocar, 5-12mm, Length 150mm, Bladeless (Obturator*1, Cannula*2) |
| | DTY01-X1 | Disposable Trocar, 5-12mm, Length 100mm (Cannula*1) |

The trocar cannula contains an internal seal to prevent loss of pneumoperitoneum when instruments are inserted or withdrawn. The seal system in the Inno-Port Disposable Bladeless Trocar is self-adjusting and accommodates instruments ranging from 5mm in diameter for trocars marked as 5mm; 5mm to 11mm in diameter for trocars marked as 11mm and 5mm to 12mm in diameter on trocars marked as 12mm. There is a stopcock valve for insufflation and rapid desufflation.

**Inno-Port Disposable Optical Trocar**

The Inno-Port Disposable Optical Trocars are available in the following configurations:

| Series | Model No. | Product Description and Specification |
|---|---|---|
| 5 mm series | DT501-7Q | Disposable Trocar, 5mm, Length 70mm, Optical (Obturator*1, Cannula*1) |
| | DT501-XQ | Disposable Trocar, 5mm, Length 100mm, Optical (Obturator*1, Cannula*1) |
| | DT501-7P | Disposable Trocar, 5mm, Length 70mm, Optical (Obturator*1, Cannula*2) |
| | DT501-XP | Disposable Trocar, 5mm, Length 100mm, Optical (Obturator*1, Cannula*2) |
| 5-11 mm series | DTW01-XQ | Disposable Trocar, 5-11mm, Length 100mm, Optical (Obturator*1, Cannula*1) |
| | DTW01-SQ | Disposable Trocar, 5-11mm, Length 150mm, Optical (Obturator*1, Cannula*1) |
| | DTW01-XP | Disposable Trocar, 5-11mm, Length 100mm, Optical (Obturator*1, Cannula*2) |
| | DTW01-SP | Disposable Trocar, 5-11mm, Length 150mm, Optical (Obturator*1, Cannula*2) |
| 5-12 mm series | DTY01-XQ | Disposable Trocar, 5-12mm, Length 100mm, Optical (Obturator*1, Cannula*1) |
| | DTY01-SQ | Disposable Trocar, 5-12mm, Length 150mm, Optical (Obturator*1, Cannula*1) |
| | DTY01-XP | Disposable Trocar, 5-12mm, Length 100mm, Optical (Obturator*1, Cannula*2) |
| | DTY01-SP | Disposable Trocar, 5-12mm, Length 150mm, Optical (Obturator*1, Cannula*2) |

The trocar cannula contains an internal seal to prevent loss of pneumoperitoneum when instruments are inserted or withdrawn. The seal system in the Inno-Port Disposable Optical Trocar is self-adjusting and accommodates instruments ranging from 5mm in diameter for trocars marked as 5mm; 5mm to 11mm in diameter for trocars marked as 11mm and 5mm to 12mm in diameter on trocars marked as 12mm. The obturator contains a scope retention mechanism. There is a stopcock valve for insufflation and rapid desufflation.

## 5 INTENDED USE

**Inno-Port Disposable Bladeless Trocar**

The Inno-Port Disposable Bladeless Trocars are intended for use in a variety of gynecologic, general thoracic and urologic endoscopic procedures to create and maintain a port of entry.

**Inno-Port Disposable Optical Trocar**

The Inno-Port Disposable Optical Trocars are intended for use in a variety of gynecologic, general thoracic and urologic endoscopic procedures to create and maintain a port of entry. The trocar may be used with or without visualization for primary and secondary insertions.

## 7 MATERIAL

All patient contacting materials have been evaluated according to ISO 10993-1 and the FDA's Guidance Use of International Standard ISO 10993-1, dated Sep. 04, 2020. All biocompatibility met the acceptance criteria.

## 8 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the proposed Inno-Port Disposable Bladeless Trocar, Inno-Port Disposable Optical Trocar, and the predicate has been performed. The results of this comparison demonstrate that the Inno-Port Disposable Bladeless Trocar, Inno-Port Disposable Optical Trocar have similar technological characteristics compared to the marketed predicate device.

| Manufactures | Taiwan Surgical Corp. | Covidien |
|---|---|---|
| Product Name | Inno-Port Disposable Bladeless Trocar and Inno-Port Disposable Optical Trocar | VersaOne™ Bladeless Trocar and Versaport™ V2 Bladeless Optical Trocar |
| Certification | -- | K151548<br>K112349<br>K130435 |
| Device Class | 2 | 2 |
| Intended use | Inno-Port Disposable Bladeless Trocar:<br>The Inno-Port Disposable Bladeless Trocars are intended for use in a variety of gynecologic, general thoracic and urologic endoscopic procedures to create and maintain a port of entry.<br><br>Inno-Port Disposable Optical Trocar:<br>The Inno-Port Disposable Optical Trocars are intended for use in a variety of gynecologic, general thoracic and urologic endoscopic procedures to create and maintain a port of entry. The trocar may be used with or without visualization for primary and secondary insertions. | VersaOne™ Bladeless Trocar:<br>The VersaOne™ Bladeless Trocars are intended for use in a variety of gynecologic, general, thoracic and urologic endoscopic procedures to create and maintain a port of entry.<br><br>Versaport™ V2 Bladeless Optical Trocar:<br>The Versaport™ V2 Bladeless Optical Trocars are intended for use in a variety of gynecologic, general, thoracic and urologic endoscopic procedures to create and maintain a port of entry. The trocar may be used with or without visualization for primary and secondary insertions. |
| Components | 5 mm: Obturator, Cannula with Self-Adjusting Seal and Stopcock. | 5 mm: Obturator, Cannula with Self-Adjusting Seal and Stopcock. |

| Manufactures | Taiwan Surgical Corp. | Covidien |
|---|---|---|
| Product Name | Inno-Port Disposable Bladeless Trocar and Inno-Port Disposable Optical Trocar | VersaOne™ Bladeless Trocar and Versaport™ V2 Bladeless Optical Trocar |
| | 5-11/12 mm: Obturator, Cannula with Self-Adjusting Seal, Specimen Removal Button, and Stopcock. | 5-11/12 mm: Obturator, Cannula with Self-Adjusting Seal, Specimen Removal Button, and Stopcock. |
| Specification | 5 mm<br>Obturator: Ø 5.8 mm<br>Cannula:<br>(1) Outer diameter: Ø 8.2 mm<br>(2) Inside diameter: Ø 6 mm<br>5-11 mm<br>Obturator: Ø 11.2 mm<br>Cannula:<br>(1) Outer diameter: Ø 13.8 mm<br>(2) Inside diameter: Ø 11.5 mm<br>5-12 mm<br>Obturator: Ø 12.8 mm<br>Cannula:<br>(1) Outer diameter: Ø 15.35 mm<br>(2) Inside diameter: Ø 13 mm | 5 mm<br>Obturator: Ø 5.85 mm<br>Cannula:<br>(1) Outer diameter: Ø 8.2 mm<br>(2) Inside diameter: Ø 6 mm<br>5-11 mm<br>Obturator: Ø 11.2 mm<br>Cannula:<br>(1) Outer diameter: Ø 13.8 mm<br>(2) Inside diameter: Ø 11.5 mm<br>5-12 mm<br>Obturator: Ø 12.8 mm<br>Cannula:<br>(1) Outer diameter: Ø 15.35 mm<br>(2) Inside diameter: Ø 13 mm |
| Packaging | Tyvek Pouch + Box | Tyvek Pouch + Box |
| Sterilization | Gamma | EO |
| Material and its Biocompatibility | In accordance with ISO 10993-1 | In accordance with ISO 10993-1 |
| Performance | Stability of Trocar:<br>1. Puncture force<br>5 mm: < 3,000 gf<br>5-11/12 mm: <5,000 gf<br>2. Removal force<br>5 mm: > 1,500 gf<br>5-11/12 mm: > 1,800 gf | Stability of Trocar:<br>1. Puncture force<br>5 mm: < 3,000 gf<br>5-11/12 mm: < 5,000 gf<br>2. Removal force<br>5 mm: > 1,500 gf<br>5-11/12 mm: > 1,800 gf |
| | Operation of Obturator:<br>1. Insertion Force<br>5 mm: < 450 gf<br>5-11/12 mm: < 1,200 gf<br>2. Withdrawal Force<br>5 mm: < 300 gf<br>5-11/12 mm: < 600 gf | Operation of Obturator:<br>1. Insertion Force<br>5 mm: < 450 gf<br>5-11/12 mm: < 1,500 gf<br>2. Withdrawal Force<br>5 mm: < 300 gf<br>5-11/12 mm: < 600 gf |
| | Airtightness of Cannula:<br>1. Stopcock Airtightness: 30s not fall | Airtightness of Cannula:<br>1. Stopcock Airtightness: 30s not fall |

| Manufactures | Taiwan Surgical Corp. | Covidien |
|---|---|---|
| Product Name | Inno-Port Disposable Bladeless Trocar and Inno-Port Disposable Optical Trocar | VersaOne™ Bladeless Trocar and Versaport™ V2 Bladeless Optical Trocar |
| | below 190 $mmH_2O$ (from 200 $mmH_2O$)<br>2. Duckbill Airtightness: 30s not fall below 190 $mmH_2O$ (from 200 $mmH_2O$)<br>3. Sealing Airtightness: 30s not fall below 150 $mmH_2O$ (from 160 $mmH_2O$) | below 190 $mmH_2O$ (from 200 $mmH_2O$)<br>2. Duckbill Airtightness: 30s not fall below 190 $mmH_2O$ (from 200 $mmH_2O$)<br>3. Sea ling Airtightness: 30s not fall below 150 $mmH_2O$ (from 160 $mmH_2O$) |
| | Durability of Cannula:<br>Pass GIA 15-times insert-out and then pass the Airtightness test. | Durability of Cannula:<br>Pass GIA 15-times insert-out and then pass the Airtightness test. |

## 9 PERFORMANCE

The bench performance tests, including Stability of Trocar, Operation of Obturator, Airtightness of Cannula, and Durability of Cannula as shown below were performed on Inno-Port Disposable Bladeless Trocar/Inno-Port Disposable Optical Trocar and its predicated device respectively. For the Additional Information (AI) Request from FDA, the performance testing of proposed product and predicated product for the evaluated representative models have been conducted, and the detailed comparison table and its differences have been updated in supplementary documents. The test results showed that both proposed devices have the similar device performance compared to the predicate device.

- Stability of Trocar
  - Puncture Force Test
  - Removal Force Test
- Operation of Obturator
  - Insertion Force
  - Withdrawal Force
- Airtightness of Cannula
  - Stopcock Airtightness
  - Duckbill Airtightness
  - Sealing Airtightness
- Durability of Cannula

## 10 CONCLUSIONS

Based on the intended use and/or indications for use, technological characteristics, performance testing and comparison to the predicate device, the Inno-Port Disposable Bladeless Trocar is substantially equivalent to the predicate device VeraPort™ V2 Bladeless Optical Trocar and the Inno-Port Disposable Optical Trocar is substantially equivalent to the predicate device VersaOne™ Bladeless Trocar.