June 2, 2026

Taiwan Surgical Corporation
Ken Chen
Official Correspondent
3F., No. 12, Sec. 12, Sheng Yi Rd., Hsinchu County
Zhubei City, TW 30261
Taiwan

Re: K252532
Trade/Device Name: Inno-Port Disposable Bladed Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: April 28, 2026
Received: April 28, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.06.02 16:17:32 -04'00'

Colin K. Chen, Ph.D.
Acting 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252532

Device Name
Inno-Port Disposable Bladed Trocar

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

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

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

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 ext. 100
Fax Number:	+886-3-6588355
Contact Person:	Ken Chen
Email:	ken.chen@twsc.com.tw
Date Prepared:	June 2, 2026

Device

Trade Name:	Inno-Port Disposable Bladed 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

Predicate Device

K151548, VersaOne™ Bladed Trocar and VersaOne™ Bladeless Trocar (Primary)
K152149, VersaOne™ V2 Bladed Trocar (Secondary)

K223593, Inno-Port Disposable Bladeless Trocar and Inno-Port Disposable Optical Trocar (Reference)

Device Description	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 Bladed 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.
Indications for Use	The Inno-Port Disposable Bladed Trocar are intended for use in a variety of gynecologic, general, thoracic and urologic endoscopic procedures to create and maintain a port of entry.
Indication for Use Comparison	The Inno-Port Disposable Bladed Trocar and the predicate devices (K152149, VersaOne™ V2 Bladed Trocar and K151548, VersaOne™ Bladed Trocar and VersaOne™ Bladeless Trocar) has the same intended use as both devices are intended for use in a variety of gynecologic, general, thoracic and urologic endoscopic procedures to create and maintain a port of entry.
Technological Comparison	The Inno-Port Disposable Bladed Trocar demonstrates substantial equivalence in terms of intended use, technological characteristics, and performance. The subject device shares identical classification, indications for use, target population, contraindications, functional characteristics, key dimensional specifications, operating environment, patient contact time, and overall design with the predicate device. Minor differences, such as the sterilization method, were identified; however, we have conducted sterilization validation to confirm the effectiveness of the sterilization process.
Non-Clinical and/or Clinical Tests Summary & Conclusion	Biocompatibility Testing: Biocompatibility testing was conducted in accordance with ISO 10993-1:2018, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process. The devices are classified as

externally communicating medical devices with contact to tissue, bone, or dentin for limited exposure (defined as cumulative single, multiple, or repeated use/contact of less than 24 hours).

Sterilization Validation:

The sterilization process was validated to achieve a Sterility Assurance Level (SAL) of 10-6 in accordance with ISO11137-1:2015 and ISO11137-2:2015.

Shelf-life

The 3-year shelf-life was established and validated through accelerated aging study conducted in accordance with ASTM F1980 and ISO11607-1/-2.

Bench Performance Testing:

Bench performance testing included evaluation of Stability of Trocar, Operation of Obturator, Airtightness of Cannula, and Durability of Cannula. The test results showed that the subject device has the similar device performance compared to the predicate device.

Conclusion

Subject device design and performance are substantially equivalent to the same of the predicate devices. Therefore, the subject device is as safe and effective as the predicate device for the requested indications for use.