August 25, 2026

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

Re: K252535
Trade/Device Name: Inno-Switch™ Laparoscopic Instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 20, 2026
Received: August 21, 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: 2026.08.25 11:13:41 -04'00'

Colin Kejing 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252535

Please provide the device trade name(s).

Inno-Switch™ Laparoscopic Instruments

Please provide your Indications for Use below.

Inno-Switch™ Laparoscopic Instruments are indicated for cutting, grasping, dissecting, and coagulating tissue in endoscopic and laparoscopic surgical procedures.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

(K252535)

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
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Contact Person:	Ken Chen
Email:	ernest.chen@twsc.com.tw
Date Prepared:	August 20, 2026

Device

Trade Name:	Inno-Switch™ Laparoscopic Instruments
Common Name:	Electrosurgical cutting and coagulation device and accessories
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Classification Name:	878.4400
Classification Product Code:	GEI
Device Class:	II

Predicate Device	K201884, ReNew XR Handpiece (Primary)
	K213127, ReNew Disposable Scissor Tips

Device Description

The Inno-Switch™ Laparoscopic Instruments are indicated for cutting, grasping, dissecting, and coagulating tissue in endoscopic and laparoscopic surgical procedures. The device features a 5mm shaft diameter designed for use with compatible trocar sleeves. The total length of the device ranges from 32 to 44 cm, accommodating different operational needs based on the selected handpiece and interchangeable tip combinations.

The fundamental scientific concept and principle of operation of the device relies on mechanical leverage, translating the surgeon's hand movements into controlled and precise actions at the distal end of the instrument through long, slender shafts. Additionally, when connected to a compatible high-frequency (HF) source, the Laparoscopic Instruments deliver unipolar electrocautery for the coagulation of tissue or minor hemorrhages.

In terms of device design and physical characteristics, the subject device is a modular system consisting of a reusable handpiece and interchangeable tips. The reusable handpiece can be further disassembled into a handle, an outer sheath, and an insert stick. The handpieces are available in various configurations, including 340mm and 420mm insert stick lengths, with options for either a standard or a ratcheted mechanism. The tips are offered in both disposable and reusable variants, featuring multiple jaw configurations such as Curved Metzenbaum Scissors, Mini Curved Metzenbaum Scissors, Fenestrated Graspers, Lapclinch Graspers, Modified Maryland Dissectors, Atraumatic Grabbers, and Right Angle Dissectors in 5mm and 10mm sizes.

The significant physical properties also encompass the materials used in the construction of the device, which include surgical-grade stainless steels (such as SUS304, SUS420, and SUS630) for the structural and active metallic components, Polyetheretherketone (PEEK) for the outer sheath and handle components. All device components are designed for direct contact with human tissue for a duration of less than 24 hours.

The reusable components are designed to be detached for re-processing, which includes cleaning and sterilization performed by medical facility prior to subsequent use. The disposable tips are provided sterile, with the devices sterilized using Ethylene Oxide (E.O.) sterilization and packaged in sterile pouches that serve as the sterile barrier system.

Indications for Use

Inno-Switch™ Laparoscopic Instruments are indicated for cutting, grasping, dissecting, and coagulating tissue in endoscopic and laparoscopic surgical procedures.

Indication for Use Comparison

The Inno-Switch™ Laparoscopic Instruments and the predicate devices (K213127 ReNew Laparoscopic Instruments Disposable Scissor Tips and K201884 ReNew XR Handpiece) has the same intended use as both devices are indicated for cutting, grasping, dissecting, and coagulating tissue in endoscopic and laparoscopic surgical procedures.

Technological Comparison

The Inno-Switch™ Laparoscopic Instruments share fundamental technological characteristics with the primary predicate device, the ReNew XR Handpiece (K201884), and the reference device, the ReNew Disposable Scissor Tips (K213127). Regarding design and actuation, both the subject and predicate devices feature a reusable handpiece that actuates interchangeable tips to cut, grasp, dissect, and coagulate tissue during endoscopic and laparoscopic procedures. Additionally, both systems utilize an electrosurgical generator to deliver high-frequency monopolar energy to the target tissue. The devices identically comply with electrical, thermal, and mechanical safety standards, including IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-2, and are both designed for a patient contact time of ≤ 24 hours.

A notable difference between the systems is the configuration of the tips; while the predicate device only offers single-use disposable tips, the Inno-Switch system provides both disposable and reusable tip options. The disposable tips for both the subject and predicate devices share identical sterilization methods, utilizing Ethylene Oxide (EO). However, the Inno-Switch reusable tips are intended to undergo repeated reprocessing by the user prior to each use, utilizing moist heat (steam) sterilization. This variation from the EO-sterilized predicate tips has been adequately addressed through validated steam sterilization testing in accordance with ISO 17665-1, demonstrating a Sterility Assurance Level (SAL) of 10^{-6}, consistent with FDA requirements.

Furthermore, while the exact material composition of the predicate devices is not publicly available for direct comparison, the Inno-Switch™ Laparoscopic Instruments are manufactured using established medical-grade materials, including SUS304, SUS420, SUS630, and PEEK. To address this difference, the subject devices have been fully evaluated for biocompatibility in accordance with the FDA-recognized ISO 10993 series of standards. The results confirmed that all materials are biocompatible and suitable for ≤ 24-hour patient contact, and no biocompatibility-related risks were identified. Ultimately, these variations in tip configuration and materials do not raise new questions of safety or effectiveness. Therefore, the Inno-Switch™ Laparoscopic Instruments are substantially equivalent to the legally marketed devices.

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).

Reprocessing and Sterilization Validation:

Reprocessing and sterilization validation were performed to ensure the safety and effectiveness of both the reusable and disposable tips of the devices. For reusable tips, reprocessing and moist heat sterilization testing were conducted in accordance with ISO 17665-1:2006, Sterilization of Health Care Products – Moist Heat – Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices, and ISO 17664:2017, Processing of Health Care Products – Information to Be Provided by the Medical Device Manufacturer for the Processing of Medical Devices. For disposable tips, Ethylene Oxide (EO) sterilization validation was conducted in accordance with ISO 11135, Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices, to ensure a sterility assurance level (SAL) of 10^{-6}.

Shelf-life:

The 3-years shelf-life for Inno-Switch™ Laparoscopic Instruments were established and validated through accelerated aging study conducted in accordance with ASTM F1980 and ISO11607-1/-2.

Electromagnetic Compatibility and Electrical Safety:

Electromagnetic compatibility (EMC) and electrical safety testing were conducted in accordance with IEC 60601-1, Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance, and IEC 60601-2-2, Medical Electrical Equipment – Part 2-2: Particular Requirements for the Basic Safety and Essential Performance of High Frequency Surgical Equipment and High Frequency Surgical Accessories. Testing was performed using a legally marketed electrosurgical generator as the energy source.

Bench Performance Testing:

Bench performance testing was conducted to evaluate the mechanical and functional integrity of the devices. The evaluations included cutting and clamping functionality, assembly and disassembly, airtight capability, electrical conductivity, rotational torque, and ratchet lever function. Comparative mechanical testing was also performed to evaluate jaw detachment torque, scissor functional capabilities (including opening/cutting forces and gauze cutting), grasping and holding forces, maximum detachment and sliding forces, force to jaw failure, and shaft bending strength. The test results showed that the subject device

demonstrated similar performance compared to the predicate device.

Ex-vivo Thermal Effects Testing:

To support the general soft tissue indication, ex-vivo thermal effects testing was conducted on liver, kidney, and skeletal muscle tissues across multiple power settings in CUT and COAG modes. The extent of thermal spread was quantified through macroscopic observation using TTC staining and microscopic histological evaluation. The results demonstrated that the subject device exhibits equivalent effectiveness in coagulation and cutting, with a comparable thermal damage profile to the predicate device across all tested tissues.

Conclusion

Based on the supporting data provided and summarized above, the Inno-Switch™ Laparoscopic Instruments demonstrate substantial equivalence to the legally marketed predicate device.