July 20, 2026

Taiwan Surgical Corporation
Ken Chen
3f., # 12, Sec. 12, Sheng Yi Rd., Hsinchu County
Zhubei City, TW 30261
Taiwan

Re: K254231
Trade/Device Name: Inno-Hook™ Disposable Clip Appliers (Ligating Clips)
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: FZP, GDO
Dated: December 22, 2025
Received: December 29, 2025

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,

TEK N. LAMICHHANE -S

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
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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)*
K254231

Device Name
Inno-Hook™ Disposable Clip Appliers (Ligating Clips)

Indications for Use *(Describe)*
The Inno-Hook™ ligating clips are non-absorbable polymer clips indicated for ligation of vessels or tissue structures.

The Inno-Hook™ Disposable Clip Applier (Ligating Clips) is indicated as the delivery device for the Inno-Hook™ ligating clips. These clip appliers are designed for use with 5mm and 10mm cannulas. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structure to be ligated so that the clip completely encompasses the vessel or tissue structure.

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
(K254231)

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:

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Email:	ernest.chen@twsc.com.tw
Date Prepared:	February 25, 2026

Device

Trade Name:	Inno-Hook™ Disposable Clip Appliers (Ligating Clips)
Common Name:	Implantable clip
Classification Name:	Clip, Implantable
Classification Name:	878.4300
Classification Product Code:	FZP, GDO
Device Class:	II

Predicate Device	K230480, Weck Auto Endo5 5mm Automatic Endoscopic 35cm Applier (AE05ML) (Primary)
	K133202, Hem-o-lok Ligating Clips (Reference)

Device Description	The Inno-Hook™ Ligating Clips are the primary therapeutic component of the device system, designed for use in general surgical procedures that require vessel or tissue ligation. These clips are non-absorbable, non-active implantable devices manufactured from a polymer material (polyoxymethylene/POM) and preloaded in the Inno-Hook™ Disposable Clip Applier during manufacture. They are designed to securely close around and maintain compression on tubular tissues to prevent hemorrhage. To accommodate different anatomical needs, the clips preloaded in the Disposable Clip Applier are available in specific sizes: the Medium-Large (ML) clips are intended for a vessel/tissue size range of 3mm to 10mm, and the Large (L) clips are intended for a vessel/tissue size range of 5mm to 13mm. The Inno-Hook™ Disposable Clip Applier serves as the delivery mechanism specifically for the Inno-Hook™ Ligating Clips. These devices are provided sterile via Ethylene Oxide (EO) sterilization for single use, and are supplied preloaded with 9, 12, or 15 Inno-Hook™ Ligating Clips. The applier automatically advances a new ligating clip when the trigger is squeezed. To correspond with the clip sizes, the clip appliers provide two shaft diameter sizes and color-coded components: a 5mm shaft (Green) for delivering ML clips, and a 10mm shaft (Purple) for delivering L clips. These are designed for introduction through applicable trocar sleeves, or larger sized trocar sleeves with a fitted converter.
Indications for Use	The Inno-Hook™ ligating clips are non-absorbable polymer clips indicated for ligation of vessels or tissue structures. The Inno-Hook™ Disposable Clip Applier (Ligating Clips) is indicated as the delivery device for the Inno-Hook™ ligating clips. These clip appliers are designed for use with 5mm and 10mm cannulas. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structure to be ligated so that the clip completely encompasses the vessel or tissue structure.
Indication for Use Comparison	The intended use of the subject device, Inno-Hook™ Disposable Clip Applier (Ligating Clips), is identical to that of the primary predicate device (Weck Auto Endo5, K230480). Both instruments are used as delivery devices for non-absorbable polymer ligating clips. Additionally,

both ligating clips are intended for use in procedures involving the ligation of vessels or tissue structures.

There are minor wording differences in the Indications for Use statements. These differences primarily reflect the specific proprietary names of the devices and accommodate the subject device's inclusion of an additional 10mm size model (indicated for use with 10mm cannulas), whereas the primary predicate specifies use with 5/5.5mm cannulas.

These minor differences do not constitute a new intended use because the fundamental therapeutic purpose—delivering non-absorbable polymer clips to completely encompass and ligate vessels or tissue structures—is exactly the same. The addition of the 10mm model merely accommodates different clinical and anatomical needs, and its functional equivalence has been fully established through comparative testing with a legally marketed reference device (Hem-o-lok Ligating Clips, K133202). Therefore, the differences in the indications for use statement do not alter the intended therapeutic effect and do not raise any new or different questions of safety and effectiveness.

Technological Comparison

The subject device, Inno-Hook™ Disposable Clip Applier (Ligating Clips), has fundamentally similar technological characteristics to the primary predicate device (Weck Auto Endo5, K230480). Both devices operate on the same mechanical principle and the implantable ligating clips for both devices are manufactured from the same non-absorbable polymer material, Polyoxymethylene (POM).

There are minor technological differences between the subject device and the primary predicate device, such as size offering, applier materials, and design feature. However, these differences do not raise any new or different questions of safety and effectiveness.

To address the 10mm size model, a legally marketed reference device (Hem-o-lok Ligating Clips, K133202) was utilized to establish functional and dimensional equivalence. A comprehensive non-clinical bench testing demonstrates that the subject device performs comparably to both the primary predicate and the reference device. Therefore, the Inno-Hook™ Disposable Clip Applier is 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 Inno-Hook™ Disposable Clip Applier (Ligating Clips) includes two types of patient-contacting components based on the nature and duration of body contact.
The first contact type consists of the clip applier jaw and shaft, which have limited contact with tissue for a duration of less than 24 hours during the surgical procedure.
The second contact type consists of the non-absorbable polymer ligating clips, which are intended to remain permanently implanted in the body and have long-term contact with tissue (>30 days).

Sterilization Validation:

The sterilization process was validated to achieve a Sterility Assurance Level (SAL) of 10-6 in accordance with ISO11135:2014.

Shelf-life:

The 3-years shelf-life for Inno-Hook™ Disposable Clip Applier (Ligating Clips) was established and validated through accelerated and real-time aging study conducted in accordance with ASTM F1980 and ISO11607-1/-2.

Bench Performance Testing:

Bench performance testing included, evaluation of clipped pull-out force, clipped slip force, airtight capability, clipped gap, stagger clip test, torque of the rotation knob, full clip test, width of the Ligating Clip after Loading, two stage sound, function of ratchet, empty indicator, clip counter, and trigger force. The test results showed that the subject device demonstrated similar performance compared to the predicate device.

Conclusion

Based on the supporting data provided and summarized above, the Inno-Hook™ Disposable Clip Applier (Ligating Clips) demonstrates substantial equivalence to the legally marketed predicate device.