January 4, 2022

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

Re: K202994
Trade/Device Name: InnoClip Disposable Clip Applier, InnoClip Clip Applier
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP, GDO
Dated: July 6, 2021
Received: July 7, 2021

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,

Deborah Fellhauer RN, BSN
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic 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)*
K202994

Device Name
InnoClip™ Disposable Clip Applier
InnoClip™ Clip Applier

Indications for Use *(Describe)*
InnoClip™ Disposable Clip Applier is indicated for patients undergoing laparoscopic surgical procedures involving occlusion of blood vessel, ducts and other tubular structures, and for radiographic marking.

The InnoClip™ Clip Applier is indicated for patients undergoing laparoscopic surgical procedures involving occlusion of blood vessel, ducts and other tubular structures, and for radiographic marking.

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.

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510(k) Summary

The Assigned 510(k) Number: K202994

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:

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Date Prepared:	December 8, 2021
Contact Person:	Ken Chen
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2 DEVICE

Trade Name:	1. InnoClip™ Disposable Clip Applier 2. InnoClip™ Clip Applier
Common Name:	Clip applier and implantable clip
Classification Panel:	79 General and Plastic Surgery
Regulation Number:	878.4300
Classification Product Code:	FZP
Device Class:	II
Additional Regulation Number:	878.4800
Additional Product Code:	GDO
Additional Device Class:	I

3 PREDICATE DEVICE

ENDO CLIP™ III 5mm Clip Applier (K121194)

4 DEVICE DESCRIPTION

InnoClip™ Disposable Clip Applier

InnoClip™ Disposable Clip Applier consists of a molded handle and trigger, a 360° rotational knob, a cartridge housing shaft and a pair of jaws which is easy for surgeon to hold the operation field in the natural position. This device includes models DC5T1-BX and DC5T1-B6 that are designed to be inserted through 5 mm trocar sleeves.

InnoClip™ Disposable Clip Applier can be used on vessels or tubular structures. The multi-fire design of InnoClip™ Disposable Clip Applier enables the surgeon to apply a maximum number of 10 clips for DC5T1-BX or 16 clips for DC5T1-B6 during a laparoscopic procedure without withdrawing and reinserting the device. The pre-loaded clips in the shaft are advanced to the jaw to enclose and occlude the target vessel by gently pulling the trigger.

InnoClip™ Clip Applier

InnoClip™ Clip Applier has two parts, Reusable Handle and a Disposable Clip Cartridge. The Reusable Handle consists of a molded handle, trigger, openable cover and a 360° rotational knob. The Disposable Clip Cartridge consists of a cartridge housing shaft and a pair of jaws which provide secured placement of the clip to the targeted vessel. The Disposable Clip Cartridge and the Reusable Handle can be easily assembled together by inserting the Disposable Clip Cartridge through a slot located in the Reusable Handle. This device includes models RC5T1-BX and RC5T1-B6 that are designed to be inserted through 5 mm trocar sleeves.

InnoClip™ Clip Applier can be used on vessels or tubular structures. The multi-fire design of InnoClip™ Clip Applier enables the surgeon to apply a maximum number of 10 clips for RC5T1-BX or 16 clips for RC5T1-B6 during a laparoscopic procedure without withdrawing and reinserting the device. The reusable handle design also reduces the surgical cost and waste. The pre-loaded clips in the Disposable Clip Cartridge are advanced to the jaw to enclose and occlude the target vessel by gently pulling the trigger.

5 INTENDED USE

InnoClip™ Disposable Clip Applier is indicated for patients undergoing laparoscopic surgical procedures involving occlusion of blood vessel, ducts and other tubular structures, and for radiographic marking.

InnoClip™ Clip Applier is indicated for patients undergoing laparoscopic surgical procedures involving occlusion of blood vessel, ducts and other tubular structures, and for radiographic marking.

6 MATERIAL

All patient contacting materials, including those with indirect patient contact, have been evaluated according to ISO 10993-1 and the FDA's Guidance Use of International Standard ISO 10993-1, dated June 16, 2016. All biocompatibility met the acceptance criteria.

7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the proposed InnoClip™ Disposable Clip Applier InnoClip™ Clip Applier, and the predicate has been performed. The results of this comparison demonstrate that the InnoClip™ Disposable Clip Applier and InnoClip™ Clip Applier have similar technological characteristics compared to the marketed predicate device.

8 PERFORMANCE

In-vitro tests conducted on a silicone tube substrate including clipped pull out force test, clip slip force test and air leakage test were performed on InnoClip™ Disposable Clip Applier and InnoClip™ Clip Applier to compared with the predicate device. The test results showed that both proposed devices have similar device performance compared to the predicate device.

In-vivo ligation tests were performed in a swine model using the InnoClip™ Disposable Clip Applier, InnoClip™ Clip Applier and the predicate device, and the results demonstrated that the proposed devices and the predicate device can ligate the target vessels and tubular tissue as its intended use.

Comparison testing was conducted on a silicone tube substrate with the InnoClip™ Disposable Clip Applier, InnoClip™ Clip Applier and predicate device to assess clip scissoring. The proposed devices met all acceptance criteria and performed as well as the predicate device.

The reusable handle of InnoClip™ Clip Applier has been validated to maintain performance functions for up to 300 times following the reprocessing methods described in the instructions for use.

9 CONCLUSIONS

Based on the intended use and/or indications for use, technological characteristics, performance testing and comparison to the predicate device, the InnoClip™ Disposable Clip Applier and InnoClip™ Clip Applier are substantially equivalent to the predicate device Endo Clip™ III.