DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 6, 2015

Taiwan Surgical Corporation
Ms. Hsiu-Ping Huang
Regulatory Specialist
3F., No. 12, Sec. 2, Sheng Yi Rd.
Zhubei City, Hsinchu County 30261
Taiwan

Re: K150259
Trade/Device Name: CLIP PLUS Disposable Clip Applier, ML
CLIP PLUS Disposable Clip Applier, L
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP, GDO
Dated: January 30, 2015
Received: October 5, 2015

Dear Ms. Huang:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150259

Device Name
CLIP PLUS Disposable Clip Applier, ML
CLIP PLUS Disposable Clip Applier, L

Indications for Use *(Describe)*
The use of the product is indicated in endoscopic procedures, including laparoscopic surgical procedures where instruments are introduced into the body through a cannula for the purpose of ligating vessels and tubular structures .

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.

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510(k) Summary

The Assigned 510(K) Number: K150259

Date Prepared: 11/06/2015

I. SUBMITTER:

Submitter:

TAIWAN SURGICAL CORPORATION

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II. DEVICE

Trade Name:

- CLIP PLUS™ Disposable Clip Applier, ML
- CLIP PLUS™ Disposable Clip Applier, L

Common Name and Classification:

Table 1. Common Name and Classification

No.	Common Name	Product Code	Classification	Regulation Section	Panel
1	Applier, surgical, clip and implantable clip	GDO FZP	I, exempt II	878.4800 878.4300	General & Plastic Surgery

III. PREDICATE DEVICE

Predicate Device 1: MICROLINE PENTAX, INC., K013695

Table 2. Predicate Device Identification

Subject Device	Predicate Device		
	Predicate Device	**Manufacturer**	**510(k) Number**
CLIP PLUS™ Disposable Clip Applier	Reusable laparoscopic clip applier with implantable titanium clip	MICROLINE PENTAX, INC.	K013695

IV. DEVICE DESCRIPTION

The Clip Applier consists of a handle piece and implantable titanium clips. The Clip Applier handle piece consists of a molded handle and trigger, a 360 degrees rotational knob, a cartridge housing shaft and a pair of jaws which provide secured placement of the clip to the desired vessel. The design enables the surgeon to apply several clips during a laparoscopic procedure without the need for withdrawing and reinserting the Clip Applier each time a clip is put in place and closed. The Clip Applier is designed to be used with a black loaded, sterile cartridge supplied in a sterile pouch. The single use disposable clip cartridge sits inside the shaft of the Clip Applier handle piece. While fully squeezing the hand piece trigger, the cartridge is inserted into the shaft through a slot located in the instrument rear.

V. INDICATIONS FOR USE

The use of the product is indicated in endoscopic procedures, including laparoscopic surgical procedures where instruments are introduced into the body through a cannula for the purpose of ligating vessels and tubular structures.

VI. PRODUCT SPECIFICATION

The shaft of the Clip Applier handle piece is sized to fit through 10mm cannula ports and the overall length of the shaft is 300mm for TDC-10-ML while the overall length of the shaft is 350mm for TDC-10-L. For TDC-10-ML, the clip length is 9mm long when closed and the clip

depth is 7.5mm; for TDC-10-L, the clip length is 10.5mm long when closed and the clip depth is 9.5mm.

VII. COMPARISION OF TECHNOLOGY CHARACTERISTICS WITH THE PRIDICATE DEVICE

Table 3. Specification Comparison Table

Features			Candidate Device	Predicate Device
			CLIP PLUSTM Disposable Clip Applier , ML/L	Microline Laparoscopic clip cartridge with implantable titanium clips, M/L -10 (K013695)
1	Hand Piece	Long tube diameter	10mm	10mm
2		Long tube length	290mm/340mm	300mm/350mm
3		Staple quantity	20	20
4		Counter	N	Y
5		Instructions	Y	Y
6		Staple fallen out prevention mechanism	N	Y
7				
8		Surgical field	15°	15°
9	Titanium Clip	Staple wire	0.9x0.6mm	0.9x0.6mm
10		Staple wide	4.3mm	4.3mm
11		Staple depth	6.9mm/9.5mm	6.9mm/9.5mm
12		Pinch flat length	9mm/10.5mm	9mm/10.5mm
13	Function	Clip Formation	Pass	Pass
		Clip Gap measurement	0.215±0.024 mm	0.223±0.005 mm
		Perpendicular Clip Pull	315±11 g	305±11 g
		Parallel Clip Pull	627±41 g	622±52 g
		Airtight Capability	Pass	Pass
14	Regulatory	Classification	class II	class I/class II

			878.4800 878.4300	878.4800 878.4300
		Intended use	Use of these products is indicated in endoscopic, including laparoscopic surgical procedures where instruments are introduced into the body through a cannula for the purpose of ligating vessels with Titanium clips.	The Microline reusable laparoscopic clip applier with implantable titanium surgical clip is intended for use to occlude vessels, ducts, tracts and other tubular structures during laparoscopic and general surgical procedures.
15	Package		Blister with Tyvek lid	Blister with Tyvek lid

VIII. PERFORMANCE DATA

- Biocompatibility：

  Because the stainless steel and titanium are standard materials for current clip applier on the market, they have been thoroughly tested in the past for biocompatibility. The product has passed the biocompatibility tests by following ISO 10993. The contact time for the device is permanent (≥ 30 days) with the body.

- Performance Testing ：

  The Bench report of Disposable Clip Applier indicates the following results. In clip formation test, the clips were all properly formed by the clip applier. In clip gap measurement, there is no significant difference between Taiwan Surgical Corporation (TWSC) and MICROLINE applier. The perpendicular clip pull test shows that the TWSC result is similar with the MICROLINE result suggested that the TWSC clips is not easily dislodged from the blood vessel. The parallel clip pull test shows that the TWSC result is similar with the MICROLINE result suggested that the TWSC clips is not easily sliding over the blood vessel. The airtight capability test result reveals that no tested clips applied to silicone tube (3.0 and 2.0 mm O.D.) allowed for any air

leakage of both clip Appliers through the air pressure from 15 to 30 PSI.

- Sterilization Verification Testing：

  The sterilization validation of gamma irradiation for disposable clip applier was successful and had met the requirements of ISO 11137-2:2012 VD max25 method on substantiation of 25kGy as a sterilization dose. This study therefore supports the multiple batch products to be irradiated at the sterilization dose kGy for a SAL of 10^{-6}.

IX. CONCULSIONS

The CLIP PLUS^{TM} Disposable Clip Applier with implantable titanium clip has the same intended use and same basic technology as the predicate device, thus is able to achieve same effectiveness and safety as the predicate device.