March 31, 2020

New Deantronics Taiwan, Ltd.
% Mr. Craig Coombs
President
Coombs Medical Device Consulting, Inc
1100 Pacific Marina, Suite 806
Alameda, California 94501

Re: K200455
Trade/Device Name: Trigger Switch and Cord
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 21, 2020
Received: February 25, 2020

Dear Mr. Coombs:

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,

Long 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

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)*
K200455

Device Name
Trigger Switch and Cord

Indications for Use *(Describe)*

The Trigger Switch and Cord are accessories that are intended for use in monopolar laparoscopic and thoracoscopic electrosurgical procedures where handswitching of laparoscopic and thoracoscopic instruments is desired.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5: 510(k) Summary

A. Device Information:

Category	Comments
Sponsor:	New Deantronics Taiwan Ltd. 12F., No.51, Sec. 4, Zhongyang Rd., TuCheng District New Taipei City 236, Taiwan R.O.C. Tel: (886) 2-2268-1726 Fax: (886) 2-2268-3800 Sponsor Contact: Ms. Jane Liu, President Email: jane@newdean.com.tw
Correspondent Contact Information:	Mr. Craig Coombs President Coombs Medical Device Consulting 1100 Pacific Marina, Suite 806 Alameda, CA 94501 Tel: 510-995-8499 Email: CraigJCoombs@gmail.com
Device Common Name:	Electrosurgical accessory Trigger Switch and Cord
Device Classification Number:	21 CFR 878.4400
Device Classification & Product Code:	Class 2, GEI
Device Proprietary Name:	Trigger Switch and Cord

Predicate Device Information:

Predicate Device:	Trigger Switch and Cord
Predicate Device Manufacturer:	Valleylab, Inc.
Predicate Device Common Name:	Electrosurgical accessory
Predicate Device Premarket Notification #	K970140
Predicate Device Classification:	21 CFR 878.4400 Electrosurgical, Cutting & Coagulation Device and Accessories
Predicate Device Classification & Product Code:	Class 2, GEI

B. Date Summary Prepared

20 March 2020

C. Description of Device

The Trigger Switch and Cord are an electrical connecting cord assembly, intended to provide an electrical path between an RF electrosurgery generator and an RF surgical electrode. The insulated wire of the Cord is 10ft long. The Cord is intended to be plugged into an in-line Trigger Switch which is attached to the RF electrode handle with an adhesive backing. The Trigger Switch allows hand switching of the electrical current through the Cord during surgery. These devices can be used in hospitals and are used by trained professionals only.

The Trigger Switch and Cord are compatible with the monopolar instruments with a shrouded 4mm male electrical connector and with an electrosurgical generator.

Typically, these application devices are used in place of foot switches in the control of the flow of electrosurgical current to the target site.

These devices are sold as sterile, single-use devices.

D. Indications for Use

The Trigger Switch and Cord are accessories that are intended for use in monopolar laparoscopic and thoracoscopic electrosurgical procedures where handswitching of laparoscopic and thoracoscopic instruments is desired.

E. Comparison to Predicate Device

As described below, the application New Deantronics Trigger Switch and Cord is substantially equivalent in intended use, technology, design and physician use to the predicate Valleylab, Inc. Trigger Switch and Cord (K970140).

Feature	**Application Device:** New Deantronics Trigger Switch and Cord (Catalog No. LC002)	**Predicate Device:** Valleylab, Inc. Trigger Switch and Cord (K970140)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
Indications for Use	The Trigger Switch and Cord are accessories that are intended for use in monopolar laparoscopic and thoracoscopic electrosurgical procedures where handswitching of laparoscopic and thoracoscopic instruments is desired.	The Trigger Switch and Cord accessories are intended for use in monopolar laparoscopic and thoracoscopic electrosurgical procedures where handswitching of laparoscopic and thoracoscopic instruments, such as scissors and graspers, is desired.	Identical, except for grammatical changes, and specific examples of instruments were dropped as unnecessary.
Product Code	GEI	GEI	Identical

Feature	**Application Device:** New Deantronics Trigger Switch and Cord (Catalog No. LC002)	**Predicate Device:** Valleylab, Inc. Trigger Switch and Cord (K970140)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
Technology			
Mechanism of Standard Electrosurgery	The Trigger Switch and Cord is designed to connect an electrosurgical generator with a monopolar instrument. When electrosurgery is activated by Trigger Switch, the electrosurgical energy will be delivery from electrosurgical generator through the Cord and to the electrode, to coagulate in surgical procedures.	The Trigger Switch and Cord is designed to connect an electrosurgical generator with a monopolar instrument. When electrosurgery is activated by Trigger Switch, the electrosurgical energy will be delivery from electrosurgical generator through the Cord and to the electrode, to coagulate in surgical procedures.	Identical
Energy Used	Radiofrequency Electrical Current	Radiofrequency Electrical Current	Identical
Operation Principle	Monopolar Electrosurgery	Monopolar Electrosurgery	Identical
Equipment Mated	Electrosurgical Generator: Force FX or Force Triad	Electrosurgical Generator: Force FX or Force Triad	Identical
Design –Mechanism			
Control Type	Hand Control	Hand Control	Identical
Cord Set Length	Trigger Cord: 10 ft Trigger Switch: 0.5 ft.	Trigger Cord: 10 ft Trigger Switch: 0.5 ft.	Identical
Design- Material			
Cable	Insulation: PVC	Insulation: PVC	Identical
	Wire: Copper (24 AWG)	Wire: Copper (24 AWG)	
Generator connector	Brass, nickel-plated female contact terminal with PVC overmold.	Identical	Identical
Monopolar instrument connector	Brass, nickel-plated female contact terminal with PVC overmold. 4mm female connector	Identical	Identical
Other Attributes			
Single Use or Reusable	Single use	Single use	Identical
Sterilized	Yes	Yes	Identical
Performance/ Safety Testing in accordance with	IEC 60601-1:2005+A1:2012 IEC 60601-1-2:2014 IEC 60601-2-2:2017 *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery: Guidance for Industry and Food and Drug Administration Staff*	IEC 601-1:1988 IEC 601-2-2:1991 AAMI HF-18:1993	Application device in conformance with latest version of the listed Standards

New Deantronics concludes that the devices are substantially equivalent.

F. Summary of Supporting Data

Electrical safety testing and bench testing has demonstrated that the performance of New Deantronics Trigger Switch and Cord meet the requirements of its pre-defined acceptance criteria and intended uses. The results of the non-clinical testing demonstrate that the Trigger Switch and Cord is as safe and effective as the predicate device.

Summary Tables of Supporting Data

Performance Data for FDA Guidance for Reviewer of Electrosurgical Device for General Surgery, issued on August 15, 2016 **Only Item B, Active Component/Accessory is applicable**					
Item	**Scope (major component or system)**	**Specification Name or Description or Test Purpose**	**Method of Verification: Standard (list), Testing Method or Audit**	**Pass / Fail?**	**Comments**
B	**Active Component/ Accessory**	Perform mechanical testing of electrosurgical instruments to minimize the risks associated with mechanical failure and short circuit	Connector pull force	Pass	This submission is an **Active Accessory** and has demonstrated the risks associated with mechanical failure and short circuit is minimized by mechanical testing before and after transit. The mechanical testing includes anchorage test and connector pull force. Also, this submission covers the devices intended to be single used rather than re-used.
			0.26kg Dynamic Strain Relief	Pass	
			10 Pound Static Strain Relief	Pass	
			Anchorage Test	Pass	

The following table summarizes the tests performed and test results. Some listed here are repeated from the Guidelines table above. The results demonstrated that the Trigger Switch and Cord is safe for its intended use and supports a finding of substantial equivalence with the predicate device.

Standard Used for Testing Protocol	**Specific Clause in Standard used for Testing Protocol**	**Test Item**	**Results**
(General Requirement)		Visual Inspection	PASS
		Continuity test	PASS
IEC 60601-1:2005+ AM1:2012	15.3.4.1	Drop Test (preconditioning)	PASS
	8.10.2	0.26kg Dynamic Strain Relief	PASS
		10 Pound Static Strain Relief	PASS
IEC 60601-2-2:2017	201.8.10.4.2	Anchorage Test	PASS
	201.8.8.3.102	HF Leakage Current Test	PASS
	201.8.8.3.103	High Frequency Dielectric Test	PASS
	201.8.8.3.104	Hi-Pot Test	PASS
		Mains Frequency Dielectric Strength Test	PASS
	201.11.6.5	Fluid Ingress Test	PASS
	201.17 202	EMC Test	PASS

A transit test validated achievement of the package and product performance criteria after ship testing. The package system performance testing per ASTM D4169 met the acceptance criteria. The results demonstrate that the device and sterile packaging is functional after shipping transportation.

G. Conclusion

After comparing the Indications for Use, technology and design of the Trigger Switch and Cord, along with all electrical safety (including IEC 60601-1: 2005 + AM1:2012; IEC 60601-1-2: 2014; IEC 60601-2-2: 2017) and performance testing, in accordance with the FDA's guidelines and FDA-recognized consensus standards for electrical safety, New Deantronics concludes that the Trigger Switch and Cord are substantially equivalent to the predicate Valleylab, Inc. Trigger Switch and Cord (K970140).