September 28, 2020

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

Re: K201221
Trade/Device Name: Electrosurgical Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 8, 2020
Received: September 9, 2020

Dear Craig 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)*
K201221

Device Name
Electrosurgical Generator

Indications for Use *(Describe)*

The Electrosurgical Generator is an electrosurgical generator containing monopolar and bipolar technology. It is intended for use with accessories during surgical procedures where the surgeon requires electrosurgical cutting and coagulating.

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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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. 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 Generator
Device Classification Number:	21 CFR 878.4400
Device Classification & Product Code:	Class II, GEI
Device Proprietary Name:	Electrosurgical Generator

Predicate Device Information:

Predicate Device:	Force FX™ electrosurgical generators
Predicate Device Manufacturer:	Covidien (formerly Valleylab, Inc.)
Predicate Device Common Name:	Electrosurgical Generator
Predicate Device Premarket Notification #	K143161
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

4 May 2020

C. Description of Device

The application device, the Electrosurgical Generator, is a solid state generator designed to supply radiofrequency electrical energy for general electrosurgical purposes, with physical dimensions around 37cm (L) x 29cm (W) x 17cm (H) and 5kg unit weight.

The Electrosurgical Generator supplies high frequency electrosurgical power from low power (<30W), medium power (Cut: 30~100W, Coag: 30~70W), to high power (Cut >100W, Coag>70W).

The Electrosurgical Generator outputs high frequency energy in the following modes:

1. Monopolar CUT:
   Pure
   Blend 1
   Blend 2

2. Monopolar COAG:
   Pin Point
   Spray

3. Bipolar:
   Standard

The Electrosurgical Generator can be activated via a hand switch or a foot switch.

The Electrosurgical Generator has a Return Electrode Contact Quality Monitor to alert the user when inadequate contact is being made with the Return (aka Neutral) Electrode.

The Electrosurgical Generator is mains powered.

D. Indications for Use

The Electrosurgical Generator is an electrosurgical generator containing monopolar and bipolar technology. It is intended for use with accessories during surgical procedures where the surgeon requires electrosurgical cutting and coagulating.

E. Comparison to Predicate Device

Feature	Application Device: Electrosurgical Generator (Model: ES300, K201221)	Predicate: Covidien Force FX™ Electrosurgical Generator (K143161)	Pertinence of Feature to Consideration of Substantial Equivalence
Indications for Use	The Electrosurgical Generator is an electrosurgical generator containing monopolar and bipolar technology. It is intended for use with accessories during surgical procedures where the surgeon requires electrosurgical cutting and coagulating.	The Force FX™ Electrosurgical Generator is an electrosurgical generator containing monopolar and bipolar technology. It is intended for use with accessories during surgical procedures where the surgeon requires electrosurgical cutting (resecting, dividing, or separating) and coagulating (hemostasis).	Identical, except specific examples of clinical techniques were dropped as unnecessary.
FDA Product Code	GEI	GEI	Identical
Operating Principle	The Electrosurgical Generator is a radio-frequency (RF) electrosurgical generator that delivers energy to compatible surgical instruments. The concentration of energy at the tip of the instrument in conjunction with tissue characteristics produces heat. The heating of tissue provides the desired surgical effect (cutting, coagulation). Variations in the waveform result in the different surgical effects achieved by different modes.	The Force FX™ is a radio-frequency (RF) electrosurgical generator that delivers energy to compatible surgical instruments. The concentration of energy at the tip of the instrument in conjunction with tissue characteristics produces heat. The heating of tissue provides the desired surgical effect (cutting, coagulation). Variations in the waveform result in the different surgical effects achieved by different modes.	Identical
Input Power	100 - 240 V	100 - 240 V	Identical
Output configuration	Isolated	Isolated	Identical
Type	CF	CF	Identical
Working theories			
Monopolar	ESU generator connects its electrosurgical electrode accessories and a neutral pad to form a cyclic circuit, the HF current generated from the generator and through the accessory to achieve CUT or COAG, and then return to generator by the neutral pad.	ESU generator connects its electrosurgical accessories and a neutral ESU pad to form a cyclic circuit, the HF current generated from the generator and through the accessory to achieve CUT or COAG, and then return to generator by the neutral pad.	Identical

Feature	Application Device: Electrosurgical Generator (Model: ES300,K201221)	Predicate: Covidien Force FX™ Electrosurgical Generator (K143161)	Pertinence of Feature to Consideration of Substantial Equivalence
Bipolar	HF current generated from the generator and the cyclic circuit formed between the two tips of the bipolar forceps, the HF power through the two tips to work on patient obtaining COAG, no need extra ESU pad.	HF current generated from the generator and the cyclic circuit formed between the two tips of the bipolar forceps, the HF power through the two tips to work on patient obtaining COAG, no need extra ESU pad.	Identical
Physical Specification			
Appearance			Different, but they do not raise new issues of safety or effectiveness.
Dimensions and weight	29.5 cm x 37.6 cm x 17.8 cm Weight: < 11.68 lb (< 5.3 kg)	35.6 cm x 35.6 cm x 11.1 cm Weight: < 18 lb (< 8.2 kg)	
Display	One 7.0” high digital display	Eight digital seven-segment displays: 0.75” high each	
Energy	HF energy	HF energy	Identical
Performance Specification			
Output mode	Monopolar CUT: Pure Blend 1 Blend 2	Monopolar CUT: Low cut Pure cut Blend	Nonclinical differences. Both the application device and predicated ones have monopolar CUT, monopolar COAG and BIPOLAR. Both of them are sinusoid as well as a similar output power under the same output mode, accordingly with the similar crest factor. The small differences have no influence on safety and performance.
	Monopolar COAG: Pin point Spray	Monopolar COAG: Low (Desiccate) Med (Fulgurate) High (Spray)	
	BIPOLAR: Standard	BIPOLAR: Low (Precise) Med (Standard) Macro	

Feature	Application Device: Electrosurgical Generator (Model: ES300, K201221)	Predicate: Covidien Force FX™ Electrosurgical Generator (K143161)	Pertinence of Feature to Consideration of Substantial Equivalence
Waveforms - Cut **Waveforms - Coag** **Waveforms - Bipolar**	Pure Cut Blend 1 Blend 2	Low Pure Blend	The frequencies are above 200 kHz, belong to High frequency range based on IEC60601-2-2 requirement; The related waveforms of the ES300 and Force FX have similar shapes, slight differences exist because of respective component parameters, which have no influence in the actual application process.
	Spray Coagulation Pin point Coagulation	Desiccate Fulgurate Spray	
	Bipolar Coagulation	Low(precise) Med(standard) Macro	
Special Functions			
Pad Control System (PCS)	The Return Electrode Contact Quality Monitor (CQM) will measure the resistance, if the resistance was beyond the range of defined by an upper and lower limit, the alarm system will be activated.	The Return Electrode Contact Quality Monitor (REM) will measure the resistance, if the resistance was beyond the range of defined by an upper and lower limit, the alarm system will be activated.	Identical
Operating	Only one output device to be activated at any given time, except for monopolar coagulation	Only one output device to be activated at any given time, except for monopolar coagulation	Identical
Audio Indicators			
Activation Tones	Yes	Yes	The frequencies are different, but it does not affect device safety and performance
Alarm Tone	Yes, Multiple	Yes, Single	The frequencies and number of tones are different, but this does not affect device safety and performance
Others			
Principal Operator	Surgeon	Surgeon	Identical
Use Location	Operating room	Operating room	Identical

Feature	Application Device: Electrosurgical Generator (Model: ES300, K201221)	Predicate: Covidien Force FX™ Electrosurgical Generator (K143161)	Pertinence of Feature to Consideration of Substantial Equivalence
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 (9 March 2020)*	IEC 60601-1:2005 IEC 60601-1-2:2007 IEC 60601-2-2:2009	Both devices were developed with the most up-to-date IEC 60601 standards at the time.

F. Summary of Supporting Data

The application Electrosurgical Generator was tested and found to be in compliance with the following standards:

Standards Body & #	Standard Name	Standard Version
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.	2005 + AMD1:2012
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.	2014
IEC 60601-2-2	Medical electrical equipment –Part 2-2: Particular requirements for the safety of high frequency surgical equipment.	2017
IEC 62304	Medical device software — Software life cycle processes	2006+ AMD 1:2015
ISTA 3A	International Safe Transit Association Procedure 3A.	2008

In addition, the Electrosurgical Generator was fully tested and in compliance with the FDA guideline *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery: Guidance for Industry and Food and Drug Administration Staff* (9 March 2020).

G. Conclusion

After comparing the Indications for Use, technology and design of the Electrosurgical Generator, 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 Electrosurgical Generator is substantially equivalent to the predicate Covidien Force FX Electrosurgical Generator (K143161).