December 19, 2019

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

Re: K193004
Trade/Device Name: Monopolar Cord
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 24, 2019
Received: October 28, 2019

Dear Mr. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or post marketing 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,

for

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)*
K193004

Device Name
Monopolar Cord

Indications for Use *(Describe)*

A Monopolar Cord is intended to be used with a compatible electrosurgical generator and an RF electrode to cut tissue and control bleeding by use of high-frequency electrical current.

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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"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, Chong Yang Rd., Tu Cheng District, New Taipei City 23675, 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 Monopolar Cord
Device Classification Number:	21 CFR 878.4400
Device Classification & Product Code:	Class 2, GEI
Device Proprietary Name:	Monopolar Cord

Predicate Device Information:

Predicate Device:	New Deantronics Foot Control Pencil
Predicate Device Manufacturer:	New Deantronics Taiwan Ltd.
Predicate Device Common Name:	Electrosurgical accessory
Predicate Device Premarket Notification #	K982749
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

13 December 2019

C. Description of Device

The Monopolar Cord, sold as sterile packaged, and ready for use devices, is intended to be used with compatible accessories to cut tissue and control bleeding by use of high-frequency electrical current.

The Monopolar Cord is compatible with the monopolar instruments with shrouded 2.5 mm female electrical connections, electrosurgical generator, and patient return electrode.

During the operation, the sterile cord should connect to the sterile accessory, and then generator connector end is inserted into the adapter and generator which it receives the high frequency current and delivers the current onto a target tissue for cutting and coagulation in a procedure. These devices can be used in hospitals and are used by trained professionally only.

D. Indications for Use

A Monopolar Cord is intended to be used with a compatible electrosurgical generator and an RF electrode to cut tissue and control bleeding by use of high-frequency electrical current.

E. Comparison to Predicate Device

As described below, the application Monopolar Cord is substantially equivalent in intended use, technology, design and physician use to the predicate New Deantronics Foot Control Pencil (K982749).

Feature	**Application Device:** Monopolar Cord (K193004)	**Predicate Device:** New Deantronics Foot Control Pencil (K982749)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
Indications for Use	A Monopolar Cord is intended to be used with a compatible electrosurgical generator and an RF electrode to cut tissue and control bleeding by use of high-frequency electrical current.	Electrosurgical accessory. A foot activated electrosurgical pencil is intended to remove tissue and control bleeding by use of high-frequency electrical current.	The Indications for Use of the application and predicate devices are the same; both devices are for use in standard cutting or coagulation. The application device does not include an attached electrode, so the specific action of the electrode is omitted.
Product Code	GEI	GEI	Identical
Technology			
Mechanism of Standard Electrosurgery	The Monopolar Cord is designed to connect a electrosurgical generator with an RF electrode. When electrosurgery is activated by foot pedal, the electrosurgical energy will be delivery from electrosurgical generator through the Cord and to the electrode, to cut or coagulate in surgical procedures	The Foot Control Pencil is designed to connect with electrosurgical generator. When electrosurgery is activated by foot pedal, the electrosurgical energy will be delivery from electrosurgical generator through the cord and to the electrode, to cut or coagulate in surgical procedures	Identical as far as the connecting cord portion is concerned
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

Feature	**Application Device:** Monopolar Cord (K193004)	**Predicate Device:** New Deantronics Foot Control Pencil (K982749)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
Required Adapter	New Deantronics AG001 adapter or Covidien E0502 Series or E0017 adapter.	New Deantronics AG001 adapter or Covidien E0502 Series or E0017 adapter.	Identical
Design –Mechanism			
Control Type	Foot Control	Foot Control	Identical
Activation Mechanism	Foot Switch	Foot Switch	Identical
Cable Set Length	10 ft	10 ft	Identical
Connection Interface	ESU: banana lead with adapter	ESU: banana lead with adapter	Identical
	Active Electrode: None. Designed to connect with monopolar instruments with shrouded 2.5 mm female electrical connections.	Active Electrode: Standard Blade	The application device is a subset of the predicate device.
Design- Electrical Feature			
Electrical Safety	Withstand 3.3kV$_p$ for **High Frequency** breakdown Withstand 3.3kV$_p$ AC at **Main Frequency (60Hz)** breakdown	Withstand 3.3kV$_p$ for **High Frequency** breakdown Withstand 3.3kV$_p$ AC at **Main Frequency (60Hz)** breakdown	Identical
Design- Material			
Handle	N/A	ABS	Different
Cable	Insulation: PE	Insulation: PE	Identical
	Colorant: Blue, PMS300	Colorant: Blue, PMS300	
	Wire: Copper	Wire: Copper	
Generator Connector (pin tip)	ESU: Brass	ESU: Brass	Identical
Active Electrode Connector	LDPE / Nickel plated brass	N/A	Different
Other Attributes			
Single Use or Reusable	Single use	Single use	Identical
Sterilization	Gamma (VDmax25)	Gamma (VDmax25)	Identical
Performance/ Electrical Safety Testing in accordance with	IEC 60601-1: 2005 + AM1:2012 IEC 60601-1-2: 2014 IEC 60601-2-2: 2017	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

A summary of the bench testing and electrical safety testing is presented on the next page.

Electrical safety testing and bench testing has demonstrated that the performance of the Monopolar Cord meets the requirements of its pre-defined acceptance criteria and intended uses. The results of the non-clinical testing demonstrate that the Monopolar 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					
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**
A	***ESU***	Provide graphical display of the output waveform	--	-	This submission is not an ESU.
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	
C	***Neutral Electrodes***	Perform the following testing	--	-	This submission does not include a Neutral Electrode
D	***Miscellaneous Components / Accessories***	Meet the design and performance specifications	--	-	The Monopolar Cord is an Active Component instead of Miscellaneous Component

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
E					
E.1	*Thermal Effects on Tissue*	Active component or electrode should demonstrate the measurement of the size of the thermal damage zone	--	-	This submission does not include an Active Electrode. This accessory is not intended to create thermal damage by itself.
E.2	*Temperature Monitoring*	The temperature sensing under simulated conditions meets design specification and performance requirements	--	-	This submission does not intend to include any temperature sensing capability.
E.3	*CQM and/or Continuity Monitoring*	Test to demonstrate the CQM and/or continuity monitoring features work as intended.	--	-	This is the requirement for ESU and Neutral Electrodes. This submission does not include both of these components.
E.4	*Capacitive Coupling*	For minimally invasive surgery application, test for active coupling resistance between the subject device and a conductive cannula/trocar device under simulated normal use condition.	--	-	This device is not for minimally invasive surgery application.

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

Monopolar Cord Electrical Testing

Standard Used for Testing Protocol	Specific Clause in Standard used for Testing Protocol	Test Description	Results
(General Mfr Requirement)		Visual Inspection	PASS
(General Mfr Requirement)		Continuity test	PASS
IEC 60601-1:2005+ AM1:2012	15.3.4.1	Drop Test (preconditioning)	PASS
IEC 60601-1:2005+ AM1:2012	8.10.2	Cable pull force from Terminal Pin	PASS
		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
IEC 60601-2-2:2017	201.8.8.3.102	HF Leakage Current Test	PASS
IEC 60601-2-2:2017	201.8.8.3.103	High Frequency Dielectric Test	PASS
IEC 60601-2-2:2017	201.8.8.3.104	Hi-Pot Test	PASS
		Mains Frequency Dielectric Strength Test	PASS
IEC 60601-2-2:2017	201.15.4.1	Connector pull force	PASS
IEC 60601-2-2:2017	201.17 202	EMC Test	PASS

The transit test was to define the product ship testing requirements and package and product performance after ship testing. The Package system performance testing per ASTM D4169 met the acceptance criteria. The results demonstrate that the Monopolar Cord is functional and remains in the sterile barrier after shipping transportation.

G. Conclusion

After comparing the Indications for Use, technology and design of the Monopolar 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 Monopolar Cord is substantially equivalent to the predicate New Deantronics Foot Control Pencil (K982749).