May 8, 2019

New Deantronics Taiwan Ltd
% Mr. Craig Coombs
Coombs Medical Device Consulting, Inc
1193 Sherman St
Alameda, California 94501

Re: K183126
Trade/Device Name: Electrosurgical accessory
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 8, 2019
Received: April 9, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Jennifer R. Stevenson
Acting Division Director
Division of General Surgery Devices
Office of Surgical and Infection Control Devices
Office of Product Evaluation & Quality
Center for Devices and Radiological Devices

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)*
K183126

Device Name
Argon Electrodes

Indications for Use *(Describe)*
The Flexible Argon Electrode is intended to be used in open or laparoscopic and thoracoscopic surgical procedures (general, neurosurgical, gynecologic) where argon-enhanced monopolar coagulation is desired.

The Retractable Argon Electrode is intended to be used in laparoscopic and thoracoscopic surgical procedures (general, neurosurgical, gynecologic) where standard monopolar electrosurgery (cutting and coagulation) or argon-enhanced monopolar coagulation is desired.

The New Deantronics Argon Electrodes have to be attached to the argon handset and are the electrosurgical electrodes applied in electrosurgical procedures.

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
Correspondent Contact Information:	Craig Coombs Coombs Medical Device Consulting 1193 Sherman Street Alameda, CA 94501 Tel: 510-337-0140
Device Common Name:	Electrosurgical accessory
Device Classification Number:	21 CFR 878.4400
Device Classification & Product Code:	Class 2, GEI
Device Proprietary Name:	New Deantronics Argon Electrodes

Predicate Device Information:

Predicate Device:	Force Argon II Argon Enhanced Electrosurgical System
Predicate Device Manufacturer:	Covidien
Predicate Device Common Name:	Electrosurgical, Cutting & Coagulation & Accessories, Argon Electrodes
Predicate Device Premarket Notification #	K964636
Predicate Device Classification:	21 CFR 878.4400
Predicate Device Classification & Product Code:	Class 2, GEI

B. Date Summary Prepared

6 May 2019

C. Description of Device

The New Deantronics Argon Electrode is designed to connect to a third-party argon handset. The electrosurgical energy is conducted from the argon handset, through the electrode to the electrosurgical target site, as is the argon gas flow. When the device is activated, the argon gas will be transformed into a plasma state flowing out of the electrode. By directly or indirectly contacting the energized electrode with the target tissue, the New Deantronics Argon Electrode can facilitate argon-enhanced coagulation, as well as standard electrosurgical cut and coagulation, as indicated .

D. Indications for Use

The **Flexible Argon Electrode** is intended to be used in open or laparoscopic and thoracoscopic surgical procedures (general, neurosurgical, gynecologic) where argon-enhanced monopolar coagulation is desired.

The **Retractable Argon Electrode** is intended to be used in laparoscopic and thoracoscopic surgical procedures (general, neurosurgical, gynecologic) where standard monopolar electrosurgery (cutting and coagulation) or argon-enhanced monopolar coagulation is desired.

The New Deantronics Argon Electrodes have to be attached to the argon handset and are the electrosurgical electrodes applied in electrosurgical procedures.

E. Comparison to Predicate Device

As described below, the application New Deantronics Argon Electrodes are substantially equivalent in intended use, technology, design and physician use to the predicate Force Argon II Argon Enhanced Electrosurgical System (K964636).

Revised Tabular Comparison of the New Deantronics Argon Electrodes to the Predicate Device

Feature	**Application Device:** New Deantronics Argon Electrode	**Predicate Device:** Force Argon II Argon Enhanced Electrosurgical System (K964636)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
Indications for Use	The **Flexible Argon Electrode** is intended to be used in open or laparoscopic and thoracoscopic surgical procedures (general, neurosurgical, gynecologic) where argon-enhanced monopolar coagulation is desired. The **Retractable Argon Electrode** is intended to be used in laparoscopic and thoracoscopic surgical procedures (general, neurosurgical, gynecologic) where standard monopolar electrosurgery (cutting and coagulation) or argon-enhanced monopolar coagulation is desired. The New Deantronics Argon Electrodes have to be attached to the argon handset and are the electrosurgical electrodes applied in electrosurgical procedures.	The Force Argon II Enhanced Electrosurgical System is intended for use in both open, laparoscopic and thoracoscopic surgical procedures (general, neurosurgical, gynecologic) where monopolar electrosurgery (cutting and coagulation) is normally used. The Force Argon II Argon Enhanced Electrosurgical System provides a controlled flow of argon to electrosurgical handset during cutting and coagulation. When the handset is activated in the gas enhanced mode, an argon gas plasma is created between the electrode and the tissue.	The Indications for Use of the application and predicate devices are nearly the same; both of these devices are for RF cutting or coagulation in laparoscopic and thoracoscopic surgical procedures (general, neurosurgical, gynecologic). We have separated out the indications for Use for the separate models of devices. We have also eliminated the last sentence in the predicate since it's not needed in the Indications for Use.
Product Code	GEI	GEI	Identical

Feature	**Application Device:** New Deantronics Argon Electrode	**Predicate Device:** Force Argon II Argon Enhanced Electrosurgical System (K964636)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
Technology			
Mechanism of Standard Electrosurgery	The retractable argon electrode is designed to be attached with an argon handset. When activated, the electrosurgical energy will be conducted from argon handset to the electrode tip, to cut or coagulate in surgical procedures	Same RF cutting and coagulation capability	Identical
Mechanism of Argon-Enhanced Operation	The argon electrode is designed to be attached with an argon handset. The hollow electrode shaft provides a gas channel for argon gas flowing through. At the distal end of electrode, the argon gas will turn into plasma state and then emit to target site.	Same as application device	Identical
Energy Used	Radiofrequency Electrical Current & Plasma thermal energy	Radiofrequency Electrical Current & Plasma Thermal Energy	Identical
Operation Principle	Monopolar Electrosurgery	Monopolar Electrosurgery	Identical
Operation Gas	Argon Gas	Argon Gas	Identical
Handpiece Mated	Covidien E2520H/E3520H	Covidien E2520H	Identical
Design – Electrode Mechanism			
Electrode Length	Flexible: 3 inch, 6 inch, 28cm Retractable: 28cm	Flexible: 7.6cm, 15cm, 28cm Retractable: 28cm	Identical
Connection Interface	Collet overlapped on argon handset nozzle	Collet overlapped on argon handset nozzle	Identical

Feature	**Application Device:** New Deantronics Argon Electrode	**Predicate Device:** Force Argon II Argon Enhanced Electrosurgical System (K964636)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
Electrode Tip Configuration	Flexible: *needle*	Flexible: *needle*	Nearly identical to predicate device, the retractable application device lacks a sharp needle electrode option
	Retractable: *blade*, *flat L*, *blunt needle*	Retractable: *blade, flat L, blunt needle, sharp needle,*	
Electrode Shaft Diameter	Flexible: 5.0 mm	Flexible: 5.0 mm	Identical
	Retractable: 4.7 mm	Retractable: 4.7 mm	
Design-Electrode Electrical Feature			
Argon Gas Flow Rate	Flexible: Maximum 13.8 LPM or 4 LPM	Flexible: 12 LPM or 4LPM	Identical
	Retractable: Maximum 4 LPM	Retractable: 4 LPM	
Electrical Safety	Withstand 13.5kV peak to peak for **High Frequency** breakdown Withstand 5.2kV RMS AC at **Main Frequency (60Hz)** breakdown	(unknown, but electrical safety complies with consensus standard)	Identical, High withstand voltage is complied with consensus standard as does the predicate devices.
Design-Electrode Material			
Electrode Insulation	Flexible: double layers of polymer	Flexible: double layers of polymer	Identical
	Retractable: single layer of polymer	Retractable: single layer of polymer	
Electrode Tip	Flexible: tungsten	Flexible: tungsten	Identical
	Retractable: tungsten or 304 stainless steel	Retractable: tungsten or 304 stainless steel	
Electrode Sheath	Flexible: aluminum tube covered by 2 layers of POF (polyolefin)	Flexible: aluminum tube covered by 2 layers of POF (polyolefin)	Identical
	Retractable: POLYGON POLYMED®	Retractable: POLYGON POLYMED®	

Feature	**Application Device:** New Deantronics Argon Electrode	**Predicate Device:** Force Argon II Argon Enhanced Electrosurgical System (K964636)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
Electrode Collet	Polycarbonate	Polycarbonate	Identical
Tip Protector	Distal: LDPE Proximal: LDPE	Flexible: Distal: PVC Proximal: LDPE Retractable: Distal: LDPE Proximal: LDPE	Functionally Identical
Other Attributes			
Single Use or Reusable	Single use	Single use	Identical
Sterilization	EtO	EtO	Identical
Performance/ Safety Testing in accordance with:	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2 IEC 60601-2-18	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	Nearly Identical, 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 Argon Electrodes meet the requirements of its pre-defined acceptance criteria and intended uses. The results of the non-clinical testing demonstrate that the New Deantronics Argon Electrodes are as safe and effective as the predicate devices.

G. Conclusion

New Deantronics concludes that the application New Deantronics Argon Electrodes are substantially equivalent in intended use, technology, design and physician use to the predicate Force Argon II Argon Enhanced Electrosurgical System (K964636).