February 19, 2019

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

Re: K183594
Trade/Device Name: Laparoscopic Hollow Electrodes:
Curved Spatula Electrode, Retractable, Aspiration Hole, 28cm ; Laparoscopic Wire J-Hook Electrode, Retractable, Aspiration Hole, 28cm ; Laparoscopic Wire L-Hook Electrode, Retractable, Aspiration Hole, 28cm; Laparoscopic Wire L-Hook Electrode, Retractable, Aspiration, 36cm ; Laparoscopic Flat L-Hook Electrode, Retractable, Aspiration Hole, 28cm ; Laparoscopic Straight Spatula Electrode, Hollow, 28cm ; Laparoscopic Curved Spatula Electrode, Hollow, 28cm; Laparoscopic Wire J-Hook Electrode, Hollow, 28cm ; Laparoscopic Wire L-Hook Electrode, Hollow, 28cm ; Laparoscopic Cylindrical Tip Electrode, Hollow, 28cm
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 20, 2018
Received: December 21, 2018

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/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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2019.02.19 15:19:41 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183594

Device Name
Laparoscopic Hollow Electrodes

Indications for Use *(Describe)*
These electrodes are intended for use in minimally invasive surgical procedures where monopolar electrosurgical cutting and coagulation are desired. Irrigation and suction capabilities via the same handset are available as well.

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.

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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."

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:	Laparoscopic Hollow Electrodes

Predicate Device Information:

Predicate Device:	Disposable Laparoscopic Electrodes, Coated and Non-coated
Predicate Device Manufacturer:	New Deantronics
Predicate Device Common Name:	Electrosurgical accessory
Predicate Device Premarket Notification #	K153265
Predicate Device Classification:	21 CFR 878.4400 Electrosurgical, Cutting & Coagulation Device and Accessories
Predicate Device Class & Product Code:	Class 2, GEI

Reference Device Information:

Reference Device:	Valleylab Laparoscopic Electrodes
Reference Device Manufacturer:	Valleylab, Inc.
Reference Device Common Name:	Electrosurgical accessory
Reference Device Premarket Notification #	K964175
Reference Device Classification:	21 CFR 878.4400 Electrosurgical, Cutting & Coagulation Device and Accessories
Reference Device Class & Product Code:	Class 2, GEI

B. Date Summary Prepared

15 Feb 2019

C. Description of Device

The New Deantronics Laparoscopic Hollow Electrodes, sold as sterile packaged, and ready for use devices, are intended for use in minimally invasive surgical procedures where monopolar electrosurgical cutting and coagulation are desired. The laparoscopic electrodes are used in conjunction with a Valleylab™ E2750 Laparoscopic Handset and 5 mm (internal diameter) or larger trocar, electrosurgical generator, and patient return electrode. During the operation, the electrode tip and the insulated shaft are to be inserted through a trocar, then conductive shaft end is inserted into the nose of an electrosurgical pencil from which it receives the high frequency current and delivers the current onto a target tissue for cutting and coagulation in a laparoscopic procedure. These devices can be used in hospitals and are used by trained professionally only.

D. Indications for Use

These electrodes are intended for use in minimally invasive surgical procedures where monopolar electrosurgical cutting and coagulation are desired. Irrigation and suction capabilities via the same handset are available as well.

E. Comparison to Predicate Device

As described below, the application New Deantronics Laparoscopic Hollow Electrodes is substantially equivalent in intended use, technology, design and physician use to the predicate New Deantronics Disposable Laparoscopic Electrodes, coated and non-coated (K153265).

Feature	**Application Device:** New Deantronics Laparoscopic Hollow Electrodes	**Predicate Device:** New Deantronics Disposable Laparoscopic Electrodes, coated and non-coated (K153265)	**Reference Device:** Valleylab Laparoscopic Handsets and Laparoscopic Electrodes (K964175)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
Indications for Use	These electrodes are intended for use in minimally invasive surgical procedures where monopolar electrosurgical cutting and coagulation are desired. Irrigation and suction capabilities via the same handset are available as well.	The disposable laparoscopic electrodes are intended for use in minimally invasive surgical procedures where monopolar electrosurgical cutting and coagulation are desired.	The Valleylab Laparoscopic Handsets (models E2750, E2751, E2750T and E2751T) and the Electrodes (model E2770 series, E2780 series, E2780R series and E2780R-ASP) are intended for use in those laparoscopic or thoracoscopic surgical procedures where the delivery of electrosurgical current, irrigation and suction via a single handset is desirable. The device is not intended to be used in endoscopic surgical procedures.	The Indications for Use of the application and predicate devices are nearly the identical; all of these devices are for RF cutting or coagulation in minimally invasive surgical procedures. The application device has irrigation and suction capabilities, but as evidenced by the reference device, these capabilities have long been applied to such devices and raise no new questions of safety or efficacy for these types of devices.
Product Code	GEI	GEI	GEI	Identical to both predicate and reference devices

Feature	**Application Device:** Laparoscopic Hollow Electrodes	**Predicate Device:** New Deantronics Disposable Laparoscopic Electrodes (K153265)	**Reference Device:** Valleylab Laparoscopic Handsets and Laparoscopic Electrodes (K964175)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
	Technology			
Mechanism of Operation	The New Deantronics Laparoscopic Hollow Electrodes combine RF technology with suction and irrigation of fluids during electrosurgical procedures.	Same RF cutting and coagulation capability	Same RF cutting and coagulation capability and same suction & irrigation capabilities as application device	Identical to predicate for RF cutting and coagulation and identical to reference for RF capabilities and suction and irrigation of fluids.
Compatible w/ RF Monopolar or Bipolar administration?	Monopolar only	Same	Same	Identical to both predicate and reference devices
Compatible Device	Valleylab™ E2750 Laparoscopic handset	Monopolar electrosurgical pencils w 0.093" (2.36mm) nozzle & w 5mm cannula or larger	Valleylab™ E2750 Laparoscopic handset	Identical to reference device; clinically equivalent to predicate device for insertion into 3rd party hand pieces
	Design			
Electrode length	***Retractable:*** 28cm and 36 cm ***Non-Retractable:*** 28cm	36cm and 45 cm	Same as application	Identical to reference device; Clinically equivalent to predicate. All sizes of all devices intended for laparoscopic applications
Electrode Outer Diameter	***Retractable:*** 5.00mm ***Non-Retractable***: 4.75mm	2.36mm shaft OD	Same as application	Identical to reference device; Clinically equivalent to predicate. All sizes of all devices intended for laparoscopic applications

Feature	**Application Device:** Laparoscopic Hollow Electrodes	**Predicate Device:** New Deantronics Disposable Laparoscopic Electrodes (K153265)	**Reference Device:** Valleylab Laparoscopic Handsets and Laparoscopic Electrodes (K964175)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
Electrode Inner Diameter	***Retractable:*** 4.10mm ***Non-Retractable:*** 3.18mm	Not Applicable	Same as application	Identical to reference device; Clinically equivalent to predicate.
Materials for Electrode Tip	SUS 304 Stainless without coating	SUS 304 Stainless with PTFE coating or without coating	SUS 304 Stainless without coating	Functional tip identical to predicate and reference devices
Materials for Electrode Sheath	***Retractable:*** PTFE, PC and POF (black) ***Non-Retractable:*** POF (black)	POF (blue)	***Retractable:*** PTFE, PC and POF (black) ***Non-Retractable:*** POF (black)	Nearly identical to predicate and reference devices
Materials for Electrode Hub (Retractable Only)	PC (Polycarbonate)	Not Applicable; No hub	PC (Polycarbonate)	Identical to reference device
Materials for Tip Protector	Distal: LDPE Proximal: LDPE	Distal: LDPE Proximal: LDPE	***Retractable*** Distal: PVC, Proximal: LDPE ***Non-Retractable*** Distal: LDPE, Proximal: LDPE	Nearly identical to predicate and reference devices

Feature	**Application Device:** Laparoscopic Hollow Electrodes	**Predicate Device:** New Deantronics Disposable Laparoscopic Electrodes (K153265)	**Reference Device:** Valleylab Laparoscopic Handsets and Laparoscopic Electrodes (K964175)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
Electrode Tip	***Retractable:*** Curved Spatula, Wire J-Hook, Wire L-Hook, Flat L-Hook ***Non-Retractable:*** Straight Spatula, Curved Spatula, Wire J-Hook, Wire L-Hook, Cylindrical Tip	Straight Spatula, Curved Spatula, Wire J-Hook, Wire L-Hook, Flat L-Hook	***Retractable:*** Curved Spatula, Wire J-Hook, Wire L-Hook, Flat L-Hook ***Non-Retractable:*** Straight Spatula, Curved Spatula, Wire J-Hook, Wire L-Hook, Cylindrical Tip, Flat L-Hook	Almost Identical, except for Non-Retractable Flat L-Hook existing in reference but not in application. All styles in application device are found in predicate device, except for cylindrical tip. Differences raise no new questions of safety or efficacy
Maximum Peak Voltage	High Frequency: 13.5kV_{p-p} Main Frequency: 5400V for 60 seconds	6300V (60Hz) for 60 seconds	5200V (60Hz) for 60 seconds	High withstand voltage is as safe as the predicate and reference devices.
	Other Attributes			
Single Use or Reusable?	Single Use	Single Use	Single Use	Identical to predicate and reference devices
Provided Sterilized?	Yes	Yes	Yes	Identical to predicate and reference devices
Sterilization Method	***Retractable:*** EtO ***Non-Retractable:*** Gamma	EtO	***Retractable:*** EtO ***Non-Retractable:*** Gamma	Identical to predicate and reference devices
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 IEC 60601-2-18	AAMI HF18-1986 IEC 601-2-2	Fundamentally Identical to predicate and reference devices, application device in conformance with latest version of the listed standards

F. Summary of Supporting Data.

New Deantronics has conducted extensive testing to ensure that the subject devices met design specification, function as intended and conform to the internationally recognized standards.

Bench Testing

All the test results demonstrate the performance of New Deantronics Laparoscopic Hollow Electrodes meet the requirements of its pre-defined acceptance criteria and intended uses. The results of the non-clinical testing demonstrate that the Laparoscopic Hollow Electrodes are as safe and effective as the predicate devices.

Performance bench testing was conducted in accordance with FDA's guidance *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery* issued August 15, 2016 and internal requirements. Suction & Aspiration testing and Thermal Effects on Tissue testing were conducted to demonstrate adequate performance within a system.

Electrical Safety and Electromagnetic Compatibility Testing

Electrical safety testing was conducted in accordance with:
IEC 60601-1:2005+AM1:2012 *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*

IEC 60601-2-2:2017 *Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*.

Electromagnetic Compatibility Testing (EMC) was conducted in accordance with: IEC 60601-1-2:2014 *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.*

The New Deantronics Laparoscopic Hollow Electrodes passed all electrical safety and EMC testing.

Shelf-Life Testing

Shelf-life testing was conducted in accordance with FDA's guidance document *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery* issued August 15, 2016 and internal requirements. The New Deantronics Laparoscopic Hollow Electrodes were subjected to accelerated aging. The aging studies established that the device and packaging remain functional and maintain sterility for 2 years.

Biocompatibility Testing

Biocompatibility testing was conducted in accordance with ISO 10993-1:2009/AC:2010, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*, and FDA's guidance documents, *Use of International Standard ISO*

10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" issued June 16, 2016 and *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery* issued August 15, 2016. This testing demonstrates that the materials in the device will not cause a biocompatibility reaction when used as intended.

Animal Studies

No animal studies were performed as appropriate verification and validation of the device was achieved from the results of the bench performance testing, biocompatibility evaluation, and electrical/safety testing.

Clinical Studies

No clinical studies were performed as appropriate verification and validation of the device was achieved from the results of the bench performance testing, biocompatibility evaluation, and electrical/safety testing.

Conclusion

It is concluded that the New Deantronics Laparoscopic Hollow Electrodes are substantially equivalent to the predicate New Deantronics Disposable Laparoscopic Electrodes, coated and non-coated (K153265).