DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

New Deantronics Taiwan, Ltd.
% Mr. Lewis Ward
L.W. Ward and Associates Incorporated
4655 Kirkwood Court
Boulder, Colorado 80301

January 5, 2016

Re: K153265
Trade/Device Name: New Deantronics Disposable Laparoscopic Electrodes, non-coated, and coated
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 13, 2015
Received: November 12, 2015

Dear Mr. Ward:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153265

Device Name
New Deantronics Disposable Laparoscopic Electrodes, non-coated and coated

Indications for Use *(Describe)*
The disposable laparoscopic electrodes are intended for use in minimally invasive surgical procedures where monopolar electrosurgical cutting and coagulation are 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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NEW DEANTRONICS
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K153265

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Date Prepared: November 13, 2015

I. Trade Name: New Deantronics Disposable, laparoscopic electrodes, non-coated and coated

II. Common Name: Electrosurgical accessory, laparoscopic electrode

III. Classification: 21 CFR 878.4400, Electrosurgical cutting and coagulation device and accessories.

IV. Product Code: GEI

V. Indications For Use:
The New Deantronics single use, laparoscopic electrodes are intended for use in minimally invasive surgical procedures where monopolar electrosurgical cutting and coagulation are desired.

VI. Predicate Device
Non-coated laparoscopic electrode
Valleylab, Inc. 510(k) K904560
Cleared for marketing on December 31, 1990.

Coated laparoscopic electrode
Megadyne Medical Products, Inc. E-Z Clean Laparoscopic Electrode
510(k) K913281
Cleared for marketing on Aug. 16, 1991.

VII. Device Description and Technological Characteristics
The disposable laparoscopic electrodes are classified by FDA as an "Electrosurgical, Cutting & Coagulation Device and Accessories", under the General & Plastic Surgery Panel, Product Code GEI, Regulation number 878.4400, Class II, panel 79. The devices are provided to healthcare professional only.

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The New Deantronics disposable laparoscopic electrodes are used in conjunction with monopolar electrosurgical pencils that accept 2.36 mm diameter shaft, 5 mm cannulas or larger cannulas with appropriate 5 mm adapters, electrosurgical generator, and patient return electrode. During the operation, the electrode tip and the insulated shaft are to be inserted through a trocar and the conductive shaft end is inserted into the nose of electrosurgical pencil from which it receives the high frequency current and delivers the current onto a target tissue for cutting and coagulation in laparoscopic procedure. The New Deantronics laparoscopic electrodes are single use.

The New Deantronics laparoscopic electrodes consists of four distinct sections, including a conductive electrode tip with part of the tip covered with PTFE insulation tube, an insulated shaft, a conductive shaft end, and an electrode tip and a shaft end protector.

There are two groups of laparoscopic electrodes, including non-coated and coated laparoscopic electrodes. The coated laparoscopic electrodes have the same configuration but the electrode tips are coated with non-sticking coating material. The devices are available in five electrode tip configurations and two different shaft lengths.

There are sixteen models of New Deantronics laparoscopic electrodes available.

Table 1. Non-coated laparoscopic electrodes

Catalog No.	Length (cm)	Coating	Electrode Tip Type
AP300-36	36	No	Straight Spatula
AP301-36	36	No	Curved Spatula
AP301-45	45	No	Curved Spatula
AP302-36	36	No	Wire J
AP303-36	36	No	Wire L
AP304-36	36	No	Flat L
AP303-45	45	No	Wire L
AP304-45	45	No	Flat L

Table 2. Coated laparoscopic electrodes

Catalog No.	Length (cm)	Coating	Electrode Tip Type
AP300-36C	36	Coated	Straight Spatula, Coated
AP301-36C	36	Coated	Curved Spatula, Coated
AP301-45C	45	Coated	Curved Spatula, Coated
AP302-36C	36	Coated	Wire J, Coated
AP303-36C	36	Coated	Wire L, Coated
AP304-36C	36	Coated	Flat L, Coated
AP303-45C	45	Coated	Wire L, Coated
AP304-45C	45	Coated	Flat L, Coated

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VIII. Non-clinical testing

New Deantronics has conducted extensive testing to ensure that the subject devices met design specification, functions as intended and conformed to the internationally recognized standards, including the following items:

(1) ISO 14971:2007, Medical devices – Application of risk management to medical devices
(2) IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
(3) 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.
(4) IEC 60601-2-2: 2009 + C1:2014, Medical electrical equipment – Part 2-2: Particular requirements for the safety of high frequency surgical equipment.
(5) ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process.
(6) ISO 10993-7:2008, Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
(7) ISO 11135:2014, Sterilization of Healthcare Products- Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.
(8) IEC 62366-1:2015, Medical devices – Part 1: Application of usability engineering to medical devices

Non-clinical testing conclusion:
All the test results demonstrate the performance of monopolar laparoscopic accessories meet the requirements of its pre-defined acceptance criteria and intended uses. The results of the non-clinical testing demonstrate that the monopolar laparoscopic electrodes is as safe and effective as the predicate devices.

IX. Substantial equivalence

The proposed devices share the same technological characteristics, technology & operating principles, performance characteristics, and configuration found in the predicate devices. There are no new technologies incorporated into the device.

The laparoscopic electrodes meet the functional claims and intended use as described in the product labeling. The safety and effectiveness are equivalent to the predicate devices identified. The claim for substantial equivalence is supported by the information provided in this submission.

Therefore, the device of this submission is substantially equivalent to the predicate devices of Valleylab, Inc. non-coated laparoscopic electrodes (K904560) and Magadyne Medical Products, Inc. coated laparoscopic electrodes (K913281).

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Table 3. Key Features Comparison to Predicates

	This Submission	Predicate Device	Predicate Device
Product name	New Deantronics Non-coated and Coated Laparoscopic Electrodes	Covidien Non-coated Laparoscopic Electrodes	Megadyne Coated Laparoscopic Electrodes
Manufacturer	New Deantronics	Covidien (formerly Valleylab)	Megadyne
510(k) #	Subject of this submission	K#904560	K#913281
Product Code	GEI	GEI	GEI
Intended use	These electrodes are intended for use in minimally invasive surgical procedures where monopolar electrosurgical cutting and coagulation are desired.	The intended use of the laparoscopic electrodes are for use in laparoscopic and thoracoscopic surgical procedures where monopolar electrosurgical cutting and coagulation are desired.	The E-Z Clean laparoscopic electrode is intended to conduct monopolar electrosurgical energy from an electrosurgical generator to target tissue during laparoscopic surgical procedures. This device is intended to be used whenever monopolar electrosurgical cutting and coagulation are indicated.
Target Population	General patients that require laparoscopic electrosurgery	General patients that require laparoscopic electrosurgery	General patients that require laparoscopic electrosurgery
Where used	Hospital	Hospital	Hospital
Energy Used	High Radiofrequency	High Radiofrequency	High Radiofrequency
Physical Dimensions and Design	Size: OD of shaft: 2.36 mm Length: 36 cm or 45 cm	Size: OD of shaft: 2.36 mm Length: 36 cm or 45 cm	Size: OD of shaft: 2.59 mm Length: 33 cm or 45 cm
Operation Principle	Monopolar electrosurgery	Monopolar electrosurgery	Monopolar electrosurgery
Shaft and shaft insulation Materials	Stainless steel shaft, polyolefin shaft insulation,	Stainless steel shaft, polyolefin shaft insulation	Stainless steel shaft, polyolefin shaft insulation
Total electrode Resistance	Less than 100 mΩ	Less than 100 mΩ	Less than 100 mΩ
Electrode tip insulation	PTFE electrode tip insulation, non-coated electrode and PTFE coated electrode	PTFE electrode tip insulation, non-coated electrode	Polyolefin electrode tip insulation, coated electrode
Tip design	Options: Straight spatula, curved spatula, J-wire, L-wire, L-flat	Options: Straight spatula, curved spatula, J-wire, L-wire, L-flat	Options: Standard blade, spatula, curved spatula, curved, L-hook, J-hook, needle, ball, O-wire,
Electrode tip coating	Non-coated and PTFE coated	Non-coated	PTFE Coated
Performance	Performs cut and coagulation, in electrosurgical procedure	Performs cut and coagulation in electrosurgical procedure	Performs cut and coagulation in electrosurgical procedure
Sterile	EO sterilization	EO sterilization	EO sterilization
Single use	Single use	Single use	Single use
Compatibility with other devices	Compatible with electrosurgical with 0.093" nozzle and with 5 mm cannula or larger	Compatible with electrosurgical with 0.093" nozzle and with 5 mm cannula or larger	Compatible with electrosurgical pencil with 0.093" nozzle and with 5 mm cannula or larger

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Electrical safety	Passes test of 6.3 kV, according to IEC 60601-2-2, 201.8.8.3.104 Capacitive coupled HF current not exceed 50 mA	Passes test of 6.3 kV, according to IEC 60601-2-2, 201.8.8.3.104 Capacitive coupled HF current not exceed 50 mA	Passes test of 6.3 kV, according to IEC 60601-2-2, 201.8.8.3.104 Capacitive coupled HF current not exceed 50 mA
Mechanical safety	Wire electrode can survive 4 bends with no crack or failure.	J-Hook electrode can survive 4 bends with no crack or failure.	J-Hook electrode can survive 4 bends with no crack or failure.
Standards met	ISO 10993-1:2009 IEC 60601-2-2:2009 ISO 11135:2014 IEC 60601-1:2005 +Amendment 1: 2012 IEC 60601-1-2:2014 ISO 14971 IEC 62366-1:2015 IEC 60601-2-18:2009 ISO 11607-1:2006 +Amendment 1:2014	ISO 10993-1 IEC 60601-2-2 ISO 11135	ISO 10993-1 IEC 60601-2-2 ISO 11135

X. Conclusion:

The New Deantronics Disposable Laparoscopic Electrode, non-coated and coated is safe and effective and performs as well as or better than the legally marketed predicates. The device is demonstrated safe and effective and meets the requirements of IEC 60601-1 Electrical Safety, IEC 60601-1-2 EMC and IAO 10993 Biocompatibility. A side by side study comparing the ND electrode to the predicate devices demonstrates substantial equivalence. A thermal Effect Study demonstrates the New Deantronics electrode performs equivalent or better than the predicates. The device is safe and effective based on the non-clinical studies.