DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 29, 2017

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

Re: K170161
Trade/Device Name: New Deantronics E Green™ Electrosurgical Monopolar Pencils
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 16, 2017
Received: March 22, 2017

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,

Jennifer R. Stevenson -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)*

K170161

Device Name

New Deantronics E Green™ Electrosurgical Monopolar Pencils

Indications for Use *(Describe)*

The New Deantronics E Green™ Electrosurgical Monopolar Pencils are intended to remove 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.

New Deantronics Group

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Section 5 510(k) Summary

Submitter:
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Date Prepared: Jan. 11, 2017

I. Trade Name: New Deantronics E Green™ Electrosurgical Monopolar Pencil

II. Common Name: Electrosurgical accessory, Electrosurgical Monopolar Pencil

III. Classification: 21 CFR 878.4400, electrosurgical cutting and coagulation device and accessories. Class 2, General and Plastic Surgery Panel 79

IV. Product Code: GEI

V. Indications for Use:
The New Deantronics E Green™ Electrosurgical Monopolar Pencils are intended to remove tissue and control bleeding by use of high-frequency electrical current.

VI. Predicate Device
510(k) 982744, New Deantronics Disposable Hand Switching Pencil, Push Button, 2 Piece With and Without Holster.

VII. Device Description and Technological Characteristics
The E Green™ Reusable Monopolar Cord is an electrosurgical accessory used with E Green™ Disposable Electrosurgical Pencil. Electrosurgical Pencils are intended to remove tissue and control bleeding by use of high-frequency electrical current.

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This product is a monopolar, electrosurgical pencil which is used for most open surgeries. The pencil can be divided in two parts, one is a gamma sterilized disposable electrosurgical pencil and another is a reusable cord which needs to be autoclaved by the user before use in a standard operating room environment. The E Green™ Reusable Monopolar Cord is used ONLY in combination with E Green™ Disposable Electrosurgical Pencil. The number of uses of the Reusable Monopolar Cord following steam sterilization is 100 times.

This device and the predicate devices have the similar technological characteristics, operating principles and performance characteristics. The proposed device is equivalent to the identified predicate device with respect to technological characteristics and function.

Table 1: New Deantronics E Green™ Reusable Monopolar Cord

Item	Catalog No.	ND P/N	Description
1	GMC01	P0001NE1	E Green™ Reusable Monopolar Cord, 10ft
2	GMC015	P0001NE2	E Green™ Reusable Monopolar Cord, 15ft

Table 2: New Deantronics E Green™ Disposable Electrosurgical Pencil

Item	Catalog No.	ND P/N	Description
1	GPEN01	P0101SE1	E Green™ Disposable Electrosurgical Pencil

VIII. Non-Clinical Testing

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.

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.

IEC 60601-2-2: 2009 + C1:2014, Medical electrical equipment – Part 2-2: Particular requirements for the safety of high frequency surgical equipment.

ISO 14971:2007, Medical Device- Application of Risk Management to Medical Devices

ISO 10993-1: 2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process.
ISO 10993-5: 2009, Biological Evaluation of Medical Devices - Part 5: Tests for *In Vitro* Cytotoxicity.
ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 10993-12: 2012, Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials.

ISO 11137-2:2013, Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose.

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ISO 11607:2006, Packaging for terminally sterilized medical devices —Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including: Amendment 1 (2014)]; Part 2: Validation requirements for forming, sealing and assembly processes [Including: Amendment 1 (2014)].

ISTA 2A Packaged-Products 150 lb (68 kg) or Less

AAMI TIR30:2011, A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.

ISO 17665-1:2006/(R) 2013, Sterilization Of Health Care Products -- Moist Heat -- Part 1: Requirements For The Development, Validation, And Routine Control Of A Sterilization Process For Medical Devices.

ANSI/AAMI ST81:2004/(R) 2010, Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices.

IEC 62366-1:2015, Medical devices -- Part 1: Application of usability engineering to medical devices

ASTM F1980-07:2011, Standard guide for accelerated aging of sterile barrier systems for medical devices. (Sterility)

Non-clinical testing conclusion:
All the test results demonstrate the performance of New Deantronics E Green™ Electrosurgical Monopolar Pencil meet the requirements of its pre-defined acceptance criteria and intended uses. The results confirm that the New Deantronics E Green™ Electrosurgical Monopolar Pencil is as safe and effective as the predicate devices.

IX. Substantial Equivalence

The New Deantronics E Green™ Electrosurgical Monopolar Pencil is substantially equivalent to the New Deantronics Disposable Hand Switching Pencil, Push Button, 2 Piece With and Without Holster (K982744) based on intended use, technology, materials, and performance. The claim of substantial equivalence is supported by information the information provided in this submission.

X. Key Features Comparison

FEATURE	New Deantronics E Green™ Electrosurgical Monopolar Pencil	New Deantronics Disposable Hand Switching Pencil, Push Button (K982744)
Intended Use	E Green™ Electrosurgical Monopolar Pencils are intended to remove tissue and control bleeding by use of high-frequency electrical current.	Electrosurgical Pencils are intended to remove tissue and control bleeding by use of high-frequency electrical current.
Use	E Green™ Disposable Electrosurgical Pencil is single use. E Green™ Reusable Monopolar Cord is reusable.	Single Use

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FEATURE	New Deantronics E Green™ Electrosurgical Monopolar Pencil	New Deantronics Disposable Hand Switching Pencil, Push Button (K982744)
Use Environment	Hospital, clinic	Hospital clinic
Dimensions	Pen body length : 12.3 cm Cord length : 10 ft and 15 ft	Pen body length : 16.2 cm Cord length : 10 ft and 15 ft
Rated Voltage	4600 V	4600 V
Material	Electrode: stainless steel, HDPE overmold Pen body: ABS, Nylon Cord: Silicone, TPV, PPSU	Electrode: stainless steel, HDPE overmold Pen body: ABS, Nylon Cord: PVC
Specification	● Button switch ● Two piece body	● Button switch ● Two piece body
Energy Source Type	RF Energy	RF Energy
Sterile method and SAL	E Green™ Disposable Electrosurgical Pencil: Gamma irradiation, SAL 10^{-6}. E Green™ Reusable Monopolar Cord: Steam, SAL 10^{-6}.	Gamma irradiation, SAL 10^{-6}.