November 20, 2020

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

Re: K202962
Trade/Device Name: Smoke Evacuation Button Switch Pencil and Telescopic Smoke Evacuation Button Switch Pencil,

Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 29, 2020
Received: September 30, 2020

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/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,

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)*
K202962

Device Name
Smoke Evacuation Button Switch Pencil and Telescopic Smoke Evacuation Button Switch Pencil

Indications for Use *(Describe)*

The Smoke Evacuation Button Switch Pencil and Telescoping Smoke Evacuation Button Switch Pencil are intended for general electrosurgical applications, including cutting and coagulation, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The Pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.

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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K202962 510(k) Summary

A. Device Information:

Category	Comments
Sponsor:	New Deantronics Taiwan Ltd. 12F., No.51, Sec. 4, Zhongyang Rd., Tucheng District New Taipei City 236, Taiwan. 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 - Electrode
Device Classification Number:	21 CFR 878.4400
Device Classification & Product Code:	Class II, GEI
Device Proprietary Name:	Smoke Evacuation Button Switch Pencil and Telescopic Smoke Evacuation Button Switch Pencil

Predicate Device Information:

Predicate Device:	Smoke Evacuation Rocker Switch Pencil and Telescoping Smoke Evacuation Rocker Switch Pencil
Predicate Device Manufacturer:	Covidien (formerly Valleylab, Inc.)
Predicate Device Common Name:	Electrosurgical Accessory - Electrode
Predicate Device Premarket Notification #	K182772
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
16 November 2020

C. Description of Device
The application devices, the Smoke Evacuation Button Switch Pencil and the Telescopic Smoke Evacuation Button Switch Pencil (referred to hereafter as the Smoke Evaluation Pencils), are a collection of electrosurgical electrodes with an integrated smoke collection tube. The flat blade electrode provided in each pencil can be removed and replaced with a compatible electrode.

New Deantronics is requesting clearance two series Smoke Evacuation Pencils.

The simplified series includes two different housing styles (round and oval) of pencil body design. Each housing style has two different lengths of attached tubing at the proximal end of the pencil body, 10ft and 15ft; thus, there are 4 models in this and the premium series. These 4 simplified series models share the same design elements (functional design, technology design, packaging, sterilization method and process, etc.)

The premium series embodies one of two extender mechanisms. There are 2 smoke nozzle extender/fixation mechanism designs in this series; with and without lock mechanism. Each design includes two lengths of spiral tube and cable, while all the other design elements, such as cosmetic appearance, grip characteristics, construction materials, packaging, sterilization method, etc., are identical in this premium series to the simplified series.

The Smoke Evacuation Pencils are designed to be used with a compatible electrosurgical generator and smoke evacuation system.

These devices are single use and are sold sterile.

D. Indications for Use
The Smoke Evacuation Button Switch Pencil and Telescoping Smoke Evacuation Button Switch Pencil are intended for general electrosurgical applications, including cutting and coagulation, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The Pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.

E. Comparison to Predicate Device

The application Smoke Evacuation Pencils and the predicate devices

Same	• Indications for Use • FDA Product Code • Electrosurgical Monopolar Energy • Operation Principle • Compatible Device • Maximum Allowable Voltage • Replaceable Coated Electrode • Ex-vivo Monopolar Thermal Effect • Sterilization Method • Single Use
Different	• Physical Dimensions • Construction Materials • Activation Switch Type • Electrode Coating • Extendable Smoke Nozzle Fixation Mechanism

None of the differences raised new questions of safety or effectiveness. New Deantronics concludes the devices are substantially equivalent.

F. Summary of Supporting Data

The application Smoke Evacuation Pencils were tested and found to be in compliance with the pertinent portions of the following standards:

Standards Body & #	Standard Name	Standard Version
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2005 + AMD1:2012
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests	2014
IEC 60601-2-2	Medical electrical equipment –Part 2-2: Particular requirements for the safety of high frequency surgical equipment	2017
ISO 10993-1	Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process.	2018
ISO 11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems;	2019
ASTM D4169	Standard Practice for Performance Testing of Shipping Containers and Systems	2016

The Smoke Evacuation Pencil was fully tested and in compliance with the FDA guideline *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery: Guidance for Industry and Food and Drug Administration Staff* (9 March 2020).

Additional performance testing, outside of that described in the standards and guidelines described above, included:

Additional Performance Test Item
Button Activation Force
Continuity & Activation switch resistance
Button activation over time
Continuity & Activation switch resistance
Activation over time
Electrode insertion/extraction force and electrode heat shrink inspection
Plug insertion/extraction force
Dynamic strain relief
Static strain relief
Adapter insertion/extraction force
Smoke tube-cable exit separation force
Smoke tube separation force
Nozzle extension/retraction force
Snap fit strength
Weld integrity test
Button retention force
Smoke tube linear force rupture
Smoke nozzle pull-out force
Electrode Wobble

G. Conclusion

After comparing the Indications for Use, technology and design of the Smoke Evacuation Pencils, 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 Smoke Evacuation Button Switch Pencil and Telescoping Smoke Evacuation Button Switch Pencil are substantially equivalent to the predicate Covidien (ValleyLab) Smoke Evacuation Rocker Switch Pencil and the Telescoping Smoke Evacuation Rocker Switch Pencil (K182772).