



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

September 17, 2015

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

Re: K152031

Trade/Device Name: Smoke Evacuation Adapter  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: Class II  
Product Code: GEI  
Dated: July 20, 2015  
Received: July 22, 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" (21CFR 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

## Indications for Use

510(k) Number (if known) K152031

Device Name  
Smoke Evacuation Adapter

### Indications for Use (Describe)

The New Deantronics Smoke Evacuation Adapter can be attached directly to an electrosurgical pencil, improving visibility and capture smoke and odors directly at the surgical site when connected to a smoke evacuator.

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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## Section 5 510(k) Summary

K152031

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#### Taiwan

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Date Prepared: July 20, 2015

#### U.S.

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Tel: (925) 280 8388

Fax: (925) 280 1788

I. Trade Name: Smoke Evacuation Adapter

II. Common Name: Electrosurgical accessory, Smoke Evacuation Adapter

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 Smoke Evacuation Adapter can be attached directly to an electrosurgical pencil, improving visibility and capture smoke and odors directly at the surgical site when connected to a smoke evacuator.

VI. Predicate Device

510(k) 945260, Valleylab Inc., Smoke Evacuation Attachment for Electrosurgical Pencils

VII. Device Description and Technological Characteristics

The Smoke Evacuation Adapter is a single-use device provided to healthcare professionals.

**Taiwan**

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This device is an accessory to an electrosurgical pencil. The Smoke Evacuation Adapter can be attached directly to an electrosurgical pencil improving visibility and capture smoke and odors directly at the surgical site when connected to a smoke evacuator. The device components include a pencil holding clamp, an electrosurgical pencil wire holder, smoke evacuator tubing pathway to the smoke evacuator, and a connector to the smoke evacuator. The clamp secures the smoke evacuation pencil adapter to the bottom of the pencil handle. Suction to remove smoke and odors is created by a smoke evacuator device furnished by the user organization. The smoke evacuator maintains a low pressure condition by a suction pump.

Four models are available, branded as “E Surgical”.

Table 1: New Deantronics Smoke Evacuation Adapters

Item	Catalog No.	ND P/N	Description
1	SA01	AE710SE1	Smoke Evacuation Adapter, with 10mm (3/8") x 20.35cm (0.70 ft) tubing with a connector to 10mm (3/8") hose, Single Use, Sterile
2	SA02	AE711SE1	Smoke Evacuation Adapter, with 10mm (3/8") x 163cm (5.5ft) tubing with a connector to 22 mm (7/8") x 145cm (5 ft) hose, Single Use, Sterile

Table 2: New Deantronics Electrosurgical Pencil with Smoke Evacuation Adapter

Item	Catalog No.	ND P/N	Description
1	PEN11SA01	PB314SE1	Button Switch Electrosurgical Pencil, Smoke Evacuation Adapter, with 10mm (3/8") x 20.35cm (0.70 ft) tubing with a connector to 10 mm (3/8") hose, Single Use, Sterile
2	PEN11SA02	PB314SE2	Button Switch Electrosurgical Pencil, Smoke Evacuation Adapter, with 10mm (3/8") x 163cm (5.5ft) tubing with a connector to 22 mm (7/8") x 145cm (5 ft) hose, Single Use, Sterile

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 60601-2-2: 2009 (Fifth Edition) + 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

IEC 62366:2007 Medical Devices – Application of Usability Engineering to Medical Devices

Non-clinical testing conclusion:

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The non-clinical tests were successfully performed on the Smoke Evacuation Adapter to demonstrate that the device is as safe, as effective, and performs as well or better than the predicate device.

**IX. Substantial Equivalence**

The Smoke Evacuation Adapter is substantially equivalent to the Valleylab (Covidien) Smoke Evacuation Attachment for Electrosurgical Pencils (K945260) based on design, intended use, technology, materials, comparison testing, and performance. Both devices require a user-furnished smoke evacuator to remove the smoke and odor.

**X. Key Features Comparison to Predicate**

<b>FEATURE</b>	<b>New Deantronics Smoke Evacuation Adapter</b>	<b>Valleylab (Covidien) Smoke Evacuation Attachment for Electrosurgical Pencils (K945260)</b>
Use Environment	Single Use, hospital, clinic	Single Use, hospital, clinic
Sterilization Method	Gamma radiation	Gamma radiation
Construction Design	Pencil holder, suction tube, wire holders, swivel connector, and connector to smoke evacuator	Pencil holder, suction tube, wire holders, swivel connector, and connector to smoke evacuator
Inlet Diameter	Approx. 10 mm	Approx. 10 mm
Material of suction tube	EVA	EVA
Connector Tube	10 mm and 22 mm	~10 mm
Materials of pencil adapter	ABS + PC	Polystyrene (PS)
Requires smoke evacuator suction device with a 10 mm or 22 mm port	10 mm and 22 mm	10 mm