May 18, 2018

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

Re: K180908
Trade/Device Name: Irrigation Tubing Bipolar Cord Sets
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 4, 2018
Received: April 6, 2018

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. 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.

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.

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,

Jennifer R. Stevenson -S3

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)*
K180908

Device Name
Irrigation Tubing Bipolar Cord Sets

Indications for Use *(Describe)*
The Irrigation Tubing Bipolar Cord Sets are intended to provide irrigation and energy simultaneously to bipolar forceps specifically designed for irrigation.

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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Section 5: 510(k) Summary

A. Device Information:

Category	Comments
Sponsor:	New Deantronics Taiwan Ltd. 12F., No.51, Sec. 4, Chong Yang Rd., Tu Cheng Dist, 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:	Irrigation Tubing Bipolar Cord Sets

Predicate Device Information:

Predicate Device:	Codman Integrated Bipolar Cord and Tubing Set
Predicate Device Manufacturer:	Codman & Shurtleff, Inc.
Predicate Device Common Name:	Electrosurgical accessory Irrigation Tubing Bipolar Cord Sets
Predicate Device Premarket Notification #	K163106
Predicate Device Classification:	21 CFR 878.4400
Predicate Device Classification & Product Code:	Class 2, GEI

B. Date Summary Prepared

4 April 2018

C. Description of Device

The Irrigation Tubing Bipolar Cord Se is designed to connect to both an electrical generator and bipolar forceps via an electrically conducting cord and to a saline source for irrigation via a catheter to provide simultaneous coagulation capabilities and irrigation capabilities.

A co-extrusion manufacturing process is applied to integrate a bipolar cord with irrigation tubing into one unit. This integrated Irrigation Tubing Bipolar Cord set are helpful to keep the bipolar electrosurgery organized.
The electrically conducting cord is formed with a pair of copper wires each coaxially surrounded by an outer insulation sheath. The insulated bipolar cord (24 AWG) provides safety protection to patients and surgical staff. The fluid catheter is formed of PVC and silicone tubing connected by connectors and is defined as fluid passage pathway.

D. Indications for Use

The Irrigation Tubing Bipolar Cord Sets are intended to provide irrigation and energy simultaneously to bipolar forceps specifically designed for irrigation.

E. Comparison to Predicate Device

As described below, the application New Deantronics Bipolar Cord Tubing Set is substantially equivalent in intended use, technology, design and physician use to the predicate Codman Integrated Bipolar Cord Tubing and Set (K163106).

Feature	**Application Device:** Irrigation Tubing Bipolar Cord Sets	**Predicate Device:** Codman Integrated Bipolar Cord Tubing and Set (K163106)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
Indications for Use	The Irrigation Tubing Bipolar Cord Sets are intended to provide irrigation and energy simultaneously to bipolar forceps specifically designed for irrigation.	The CODMAN Integrated Bipolar Cord and Tubing Sets are intended to provide irrigation and energy simultaneously to bipolar forceps specifically designed for irrigation.	The Indications for Use of the two devices are identical, except for name of the devices
Product Code	GEI	GEI	Identical
Technology			
Mechanism of Operation	The integrated Bipolar Cord Set and Irrigation tubing is designed to connect an RF electrical generator to bipolar coagulating forceps via an electrically conducting cord. It is also intended to connect a saline source, via the irrigation tubing. The saline flow through the tubing is controlled by a surgeon-controlled fluid	Same	Identical

Feature	**Application Device:** Irrigation Tubing Bipolar Cord Sets	**Predicate Device:** Codman Integrated Bipolar Cord Tubing and Set (K163106)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
	controller. This allows for simultaneous, controlled, coagulation and irrigation capabilities.		
Compatible w/ Monopolar or Bipolar RF administration?	Bipolar only	Bipolar only	Identical
Integral Electrical Cable and Fluid Tubing?	Yes	Yes	Identical
Fluid feed compatibility	Rotary or Gravity	Rotary or Gravity	Identical
Design – Electrical Cable			
Cable length	3.6 meters	3.4 meters	Functionally Identical
Wire Gauge	24 AWG	24 AWG	Identical
Materials for cable insulation	PVC	PVC	Identical
Generator plug design	Electrodes Consolidated into a single plug with banana plug connectors	Two separate plugs with banana plug connectors	Visually different but electrically identical.
Plug Overmold	PVC	PVC	Identical
Design – Saline Tubing			
Tubing length	4.4 meters	4.8 meters	Functionally identical
Materials for irrigation tubing	PVC and silicone	PVC and silicone	Identical
Tubing Inner Diameter	PVC: 3.0 mm Silicone (Gravity Feed): 3.0 mm Silicone (Rotary Pump): 0.8 mm	PVC: 3.0 mm Silicone (Gravity Feed): 3.0 mm Silicone (Rotary Pump): 0.8mm	Identical
Tubing Flow rate (Rotary type)	Min: 1.15cc/min (+/-30%) Max: 16 cc/min (+/-30%)	Min: 1.15cc/min (+/-30%) Max: 16 cc/min (+/-30%)	Identical
Tubing Flow rate (Gravity type)	Min: < 6 cc/min Max: > 21 cc/min	Min: < 6 cc/min Max: > 21 cc/min	Identical
Proximal Spike adapter for Saline source	ABS	ABS	Identical

Feature	**Application Device:** Irrigation Tubing Bipolar Cord Sets	**Predicate Device:** Codman Integrated Bipolar Cord Tubing and Set (K163106)	**Pertinence of Feature to Consideration of Substantial Equivalence.**
Tubing Sections Adaptor	PVC	PVC	Identical
Tubing Clamp	Polypropylene	Celanese and Polyacetal	These materials do not come in contact with the patient or the saline stream. Both clamps have identical functionality. No new questions of safety or efficacy are raised by the material differences.
Other Attributes			
Single Use or Reusable?	Single Use	Single Use	Identical
Provided Sterilized?	Yes	Yes	Identical
Performance/ Safety Testing in accordance with:	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	Identical

New Deantronics concludes that the devices are substantially equivalent.

F. Summary of Supporting Data

Electrical safety testing and bench testing has demonstrated that the performance of New Deantronics Irrigation Tubing Bipolar Cord Sets meet the requirements of its pre-defined acceptance criteria and intended uses. The results of the non-clinical testing demonstrate that the irrigation tubing bipolar cord sets are as safe and effective as the predicate devices.

New Deantronics concludes that the New Deantronics Irrigation Tubing Bipolar Cord Sets are substantially equivalent to the predicate Codman Integrated Bipolar Cord Tubing and Set (K163106).