



June 29, 2026

New Deantronics Taiwan Ltd.  
Hung-Kuei Tsai  
Regulatory Specialist  
12F, No. 51, Sec. 4, Zhongyang Rd.,  
Tucheng Dist., New Taipei City, 236  
Taiwan

RE: K251492

Trade/Device Name: Irrigation Tubing Bipolar Cord Set  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories  
Regulatory Class: Class II  
Product Code: GEI  
Dated: November 26, 2025  
Received: November 26, 2025

Dear Hung-Kuei Tsai:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Colin K.  
Chen -S**

Digitally signed by  
Colin K. Chen -S  
Date: 2026.06.29  
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Colin K. Chen, Ph.D.  
Acting Assistant Director  
DHT4A: Division of General Surgery Devices  
OHT4: Office of Surgical and  
Infection Control Devices  
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Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K251492

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                                                                                                                                                           |
|-----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Submitter:                              | New Deantronics Taiwan Ltd.<br>12F. No.51, Sec. 4, Zhongyang Rd., Tucheng Dist.,<br>New Taipei City, 236 Taiwan                                                    |
| Contact Information:                    | Mr. Hungkuei.Tsai<br>12F. No.51, Sec. 4, Zhongyang Rd., Tucheng Dist.,<br>New Taipei City, 236 Taiwan<br>Tel: 886-2 2268 1726 ext.1542<br>Email: RA@newdean.com.tw |
| Common Name                             | Electrosurgical cutting and coagulation device<br>and accessories                                                                                                  |
| Classification Number                   | 21 CFR 878.4400                                                                                                                                                    |
| Device Classification &<br>Product Code | Class II, GEI                                                                                                                                                      |
| Proprietary Name                        | Irrigation Tubing Bipolar Cord Sets                                                                                                                                |

### Predicate Device Information:

|                                         |                                                                   |
|-----------------------------------------|-------------------------------------------------------------------|
| Predicate Device                        | Sterile Single Use Irrigation Bipolar Cable                       |
| Manufacturer                            | Modern Medical Equipment Manufacturing, LTD.                      |
| Common Name                             | Electrosurgical cutting and coagulation device and<br>accessories |
| Premarket Notification #                | K211170                                                           |
| Classification Number                   | 21 CFR 878.4400                                                   |
| Device Classification & Product<br>Code | Class 2, GEI                                                      |

### Reference Device:

|                          |                                                                   |
|--------------------------|-------------------------------------------------------------------|
| Reference Device         | Irrigation Tubing Bipolar Cord Sets                               |
| Manufacturer             | New Deantronics Taiwan Ltd.                                       |
| Common Name              | Electrosurgical cutting and coagulation device and<br>accessories |
| Premarket Notification # | K180908                                                           |

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|                       |                 |
|-----------------------|-----------------|
| Classification Number | 21 CFR 878.4400 |
| Class & Product Code  | Class 2, GEI    |

**B. Date Summary Prepared**

June 29, 2026

**C. Device Description**

The Irrigation Tubing Bipolar Cord Set is packaged sterile and has a fluid pathway. A single-use bipolar cord and irrigation tubing are integrated into one set. The 12-foot cord set consists of a solid plug / separated lead, a female socket connector for forceps, an inlet spike with a cap, an on/off clamp, silicone tubing and fitting connectors, and a male luer connector. This integrated set provides the system with a one-unit delivery conduit and cable for carrying irrigating solution and electrosurgical energy to the bipolar irrigating forceps for coagulation and irrigation of tissue simultaneously.

This Irrigation Tubing Bipolar Cord Set is compatible with bipolar irrigating forceps with a 2-pin plug (standard insulated and non-insulated forceps or equivalent irrigating forceps) and an electrosurgical generator with bipolar mode.

**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 with the Predicate Device**

This section presents the justification for the substantial equivalence between the proposed device (New Deantronics Irrigation Tubing Bipolar Cord Set) and the predicate device (Sterile Single Use Irrigation Bipolar Cable, K211170). A detailed tabular comparison is provided below.

| Feature                | Subject Device:<br>New Deantronics<br>Irrigation Tubing<br>Bipolar Cord Set                                                                                   | Predicate Device<br>(K211170): Sterile<br>Single Use Irrigation<br>Bipolar Cable                                                                                                                                                                                                                    | Reference Device<br>(K180908): New<br>Deantronics Irrigation<br>Tubing Bipolar Cord Set                                                                       | Substantial<br>Equivalence<br>Comparison                                                                                                                                               |
|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Indications for<br>Use | The Irrigation Tubing Bipolar Cord Sets are intended to provide irrigation and energy simultaneously to bipolar forceps specifically designed for irrigation. | The device is intended to provide irrigation and energy simultaneously to standard bipolar forceps specifically designed for irrigation. The device is used with Malis bipolar coagulators or the compatible generators and the Malis CMC-II Irrigation Module or The Malis Irrigation Module 1000. | The Irrigation Tubing Bipolar Cord Sets are intended to provide irrigation and energy simultaneously to bipolar forceps specifically designed for irrigation. | Same. Both the subject and predicate devices provide simultaneous irrigation and energy delivery to bipolar forceps designed for irrigation and are only compatible with bipolar mode. |
| Target<br>Population   | General patients that require bipolar electrosurgery with fluid irrigation during surgical procedure                                                          | General patients that require bipolar electrosurgery with fluid irrigation during surgical procedure                                                                                                                                                                                                | General patients that require bipolar electrosurgery with fluid irrigation during surgical procedure                                                          | Identical to both the predicate and reference devices                                                                                                                                  |
| Product Code           | GEI                                                                                                                                                           | GEI                                                                                                                                                                                                                                                                                                 | GEI                                                                                                                                                           | Identical to both the predicate and reference devices                                                                                                                                  |
| Category               | <b>BI101-1G:</b><br>Cord & Tubing set, Gravity Feed, Solid Plug, Single use                                                                                   | <b>CD933:</b><br>Cord & Tubing set, Fixed Plug, Gravity Feed                                                                                                                                                                                                                                        | <b>BI101-1G:</b><br>Cord & Tubing set, Gravity Feed, Solid Plug, Single use                                                                                   | The model configuration of the device is the same as that of the predicate device.                                                                                                     |
|                        | <b>BI101-1R:</b><br>Cord & Tubing set, Rotary Pump, Solid Plug, Single Use                                                                                    | <b>CD933:</b><br>Cord & Tubing set, Fixed Plug, Rotary Pump.                                                                                                                                                                                                                                        | <b>BI101-1R:</b><br>Cord & Tubing set, Rotary Pump, Solid Plug, Single Use                                                                                    |                                                                                                                                                                                        |
|                        | <b>BI102-2G:</b><br>Cord & Tubing set, Separated Lead, Gravity Feed, Single Use                                                                               | <b>CD933:</b><br>Cord & Tubing set, Flying Lead, Gravity Feed                                                                                                                                                                                                                                       |                                                                                                                                                               |                                                                                                                                                                                        |
|                        | <b>BI102-2R:</b><br>Cord & Tubing set, Separated Lead, Rotary Pump, Single Use                                                                                | <b>CD933:</b><br>Cord & Tubing set, Flying Lead, Rotary Pump.                                                                                                                                                                                                                                       |                                                                                                                                                               |                                                                                                                                                                                        |
| Technology             |                                                                                                                                                               |                                                                                                                                                                                                                                                                                                     |                                                                                                                                                               |                                                                                                                                                                                        |
| Energy Source          | Radiofrequency                                                                                                                                                | Radiofrequency                                                                                                                                                                                                                                                                                      | Radiofrequency                                                                                                                                                | Identical to both the predicate and reference devices                                                                                                                                  |

| Feature                                                          | Subject Device:<br>New Deantronics<br>Irrigation Tubing<br>Bipolar Cord Set                                                                                                                                                                                                                                                                                                                                  | Predicate Device<br>(K211170): Sterile<br>Single Use Irrigation<br>Bipolar Cable                                                                                                                                                                                                                                                                                                                                  | Reference Device<br>(K180908): New<br>Deantronics Irrigation<br>Tubing Bipolar Cord Set                                                                                                                                                                                                                                                                                                                               | Substantial<br>Equivalence<br>Comparison                                                                                                                                                        |
|------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Operation Principle                                              | The Irrigation Tubing Bipolar Cord Set 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 irrigation tubing. The saline flow through the tubing is controlled by a surgeon-operated fluid controller. This allows for simultaneous controlled coagulation and irrigation capabilities. | Sterile Single Use Irrigation Bipolar Cable 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 irrigation tubing. The saline flow through the tubing is controlled by a surgeon-operated fluid controller. This allows for simultaneous controlled coagulation and irrigation capabilities. | The Irrigation Tubing Bipolar Cord Set 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 controller. This allows for simultaneous, controlled, coagulation and irrigation capabilities. | Identical to both the predicate and reference devices                                                                                                                                           |
| Energy Delivery                                                  | Bipolar only                                                                                                                                                                                                                                                                                                                                                                                                 | Bipolar only                                                                                                                                                                                                                                                                                                                                                                                                      | Bipolar only                                                                                                                                                                                                                                                                                                                                                                                                          | Identical to both predicate and reference devices                                                                                                                                               |
| Integral Electrical Cable and Fluid Tubing                       | Yes                                                                                                                                                                                                                                                                                                                                                                                                          | Yes                                                                                                                                                                                                                                                                                                                                                                                                               | Yes                                                                                                                                                                                                                                                                                                                                                                                                                   | Identical to both predicate and reference devices                                                                                                                                               |
| Devices for which this equipment or accessory is to be used with | New Deantronics Irrigation Tubing Bipolar Cord Set is used with electrosurgical generator with bipolar mode or bipolar electrosurgical generator, along with gravity pumps or rotary irrigation modules.                                                                                                                                                                                                     | The Sterile Single Use Irrigation Bipolar Cable is used with Malis bipolar coagulators or the compatible generators and the Malis CMC-II Irrigation Module or the Malis Irrigation Module 1000.                                                                                                                                                                                                                   | New Deantronics Irrigation Tubing Bipolar Cord Set is used with electrosurgical generator with bipolar mode or bipolar electrosurgical generator, along with gravity pumps or rotary irrigation modules.                                                                                                                                                                                                              | Both the subject and predicate devices require connection to a bipolar electrosurgical generator or a multi-mode electrosurgical generator in bipolar mode and are compatible with gravity pump |

| Feature                         | Subject Device:<br>New Deantronics<br>Irrigation Tubing<br>Bipolar Cord Set                                                                                                                                                                                                                                                                                                                                                  | Predicate Device<br>(K211170): Sterile<br>Single Use Irrigation<br>Bipolar Cable                                                                                                                                                                                                                                                                                                                                       | Reference Device<br>(K180908): New<br>Deantronics Irrigation<br>Tubing Bipolar Cord Set | Substantial<br>Equivalence<br>Comparison                                                                                                                                        |
|---------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                 |                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                         | irrigation (e.g.,<br>Malis CMC-II<br>Irrigation Module)<br>or rotary pump<br>irrigation (Malis<br>Irrigation Module<br>1000).                                                   |
| Fluid feed<br>compatibility     | Rotary or gravity                                                                                                                                                                                                                                                                                                                                                                                                            | Rotary or gravity                                                                                                                                                                                                                                                                                                                                                                                                      | Rotary or gravity                                                                       | Identical to both<br>the predicate and<br>reference devices                                                                                                                     |
| <b>Design – Mechanism</b>       |                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                         |                                                                                                                                                                                 |
| Construction<br>Design          | This device<br>integrates a<br>bipolar cord and an<br>irrigation tube.                                                                                                                                                                                                                                                                                                                                                       | The device integrates a<br>bipolar cord and an<br>irrigation tube.                                                                                                                                                                                                                                                                                                                                                     | The device integrates a<br>bipolar cord and an<br>irrigation tube.                      | Identical to both the<br>predicate and<br>reference devices                                                                                                                     |
|                                 | One end of the<br>bipolar cord is the<br>generator plug; the<br>other end is a female<br>socket connector.<br>One terminal of the<br>irrigation tube is<br>inlet spike with<br>protective cap; the<br>other terminal is the<br>male luer connector<br>with protective cap.<br>A pinch clamp is<br>located along the<br>tubing, and silicone<br>tubing is<br>interconnected to<br>the irrigation tube<br>via a tube connector | One end of the bipolar<br>cord is the generator<br>plug; the other end is a<br>female socket connector.<br>One terminal of the<br>irrigation tube is inlet<br>spike with protective<br>cap; the other terminal is<br>the male luer connector<br>with protective cap. A<br>pinch clamp is located<br>along the tubing, and a<br>silicone tubing is<br>interconnected to the<br>irrigation tube via a tube<br>connector. | Identical to the subject<br>device                                                      | Identical to the<br>reference device                                                                                                                                            |
| Generator Plug<br>Configuration | Fixed (Solid) Plug,<br>Separated Lead                                                                                                                                                                                                                                                                                                                                                                                        | Fixed Plug, Flying Lead                                                                                                                                                                                                                                                                                                                                                                                                | Fixed (Solid) Plug                                                                      | The generator plug<br>design for both the<br>subject and<br>predicate devices<br>share the same<br>technological<br>characteristics,<br>each incorporating<br>both a fixed plug |

| Feature                                        | Subject Device:<br>New Deantronics<br>Irrigation Tubing<br>Bipolar Cord Set       | Predicate Device<br>(K211170): Sterile<br>Single Use Irrigation<br>Bipolar Cable  | Reference Device<br>(K180908): New<br>Deantronics Irrigation<br>Tubing Bipolar Cord Set | Substantial<br>Equivalence<br>Comparison                                   |
|------------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
|                                                |                                                                                   |                                                                                   |                                                                                         | and a separated<br>lead configuration<br>for the electrical<br>connection. |
| <b>Design - Electrical Feature</b>             |                                                                                   |                                                                                   |                                                                                         |                                                                            |
| Rated accessory<br>voltage                     | 550 V <sub>p</sub>                                                                | 500 V <sub>p</sub>                                                                | 550 V <sub>p</sub>                                                                      | Identical to<br>reference device                                           |
| <b>Design - Material</b>                       |                                                                                   |                                                                                   |                                                                                         |                                                                            |
| Materials for<br>irrigation tubing             | PVC and silicone                                                                  | PVC                                                                               | PVC and silicone                                                                        | Identical to the<br>reference device                                       |
| Plug Overmold                                  | PVC                                                                               | PVC                                                                               | PVC                                                                                     | Identical to both<br>the predicate and<br>reference devices                |
| Plug Pin                                       | Brass                                                                             | Brass                                                                             | Brass                                                                                   | Identical to both<br>the predicate and<br>reference devices                |
| Male Luer<br>Connector                         | PVC                                                                               | PC                                                                                | PVC                                                                                     | Identical to the<br>reference device                                       |
| Proximal Spike<br>adapter for<br>Saline source | ABS                                                                               | ABS                                                                               | ABS                                                                                     | Identical to both<br>the predicate and<br>reference devices                |
| Fitting Connector                              | PVC                                                                               | PVC                                                                               | PVC                                                                                     | Identical to both                                                          |
| Tubing Clamp                                   | PP (Polypropylene)                                                                | PP (Polypropylene)                                                                | PP (Polypropylene)                                                                      | Identical to both                                                          |
| <b>Performance Attributes</b>                  |                                                                                   |                                                                                   |                                                                                         |                                                                            |
| Single Use or<br>Reusable                      | Single use                                                                        | Single use                                                                        | Single use                                                                              | Identical to both                                                          |
| Sterilization                                  | Ethylene Oxide                                                                    | Ethylene Oxide                                                                    | Ethylene Oxide                                                                          | Identical to both                                                          |
| Shelf life                                     | 5 years                                                                           | 3 years                                                                           | 5 years                                                                                 | Identical to<br>reference device                                           |
| Applicable ES and<br>EMC Standard              | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-2-2<br>(except subclause<br>201.12.2 f) | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-2-2<br>(except subclause<br>201.12.2 f) | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-2-2                                           | Identical to<br>predicate                                                  |

## F. Summary of Non-Clinical and/or Clinical Tests

Both the Irrigation Tubing Bipolar Cord Set and its sterile barrier packaging were evaluated to verify performance and safety in accordance with applicable standards, as shown in the table below.

| Device                 |                                                                                                                                                                                                                                                                                                                                                                                       |
|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| BI101-1G<br>BI102-2G   | Continuity/ Lead to Lead Electrical Isolation/ Tubing Set Leakage/ Tubing Set Flow Rate/ Generator Plug Insertion/Extraction Force/ Forceps Plug Insertion/ Extraction Force/ Pull Test of Tubing Set/ Silicone Tubing Endurance Test/ Anchorage Test/ HF Leakage/ HF Dielectric Strength/ Main Frequency Dielectric Strength/ Main Frequency Dielectric Strength Test/               |
| BI101-1R<br>BI102-2R   | Continuity/ Lead to Lead Electrical Isolation/ Tubing Set Leakage/ Tubing Set Flow Rate/ Generator Plug Insertion/Extraction Action Force/ Forceps Plug Insertion/ Extraction Action Force / Pull Test of Tubing Set/ Silicone Tubing Endurance Test/ Anchorage Test/ HF Leakage/ HF Dielectric Strength/ Main Frequency Dielectric Strength/ Main Frequency Dielectric Strength Test |
| Package                |                                                                                                                                                                                                                                                                                                                                                                                       |
| Inspection and Testing | Package and Device Integrity/ Label Visibility/ Peel Open/ Seal Width/ Burst Test/ Bubble Leak/ Dye Leak                                                                                                                                                                                                                                                                              |

Testing was conducted in accordance with the following applicable standards and FDA guidance document, and the results met the specified requirements and recommendations:

| Standards        | Title                                                                                                                                                                                       | Version                     |
|------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| IEC 60601-1      | Medical electrical equipment - Part 1: General requirements and essential performance                                                                                                       | 2005 + AMD1:2012 +AMD2:2020 |
| 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 basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories | 2017 + AMD1:2023            |
| IEC TR 60601-4-2 | Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems                 | 2016                        |

| Standards    | Title                                                                                                                                                                    | Version           |
|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| ISO 10993-1  | Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process                                                               | 2018              |
| ISO 10993-5  | Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity                                                                                         | 2009              |
| ISO 10993-7  | Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals                                                                                | 2008+AMD 1:2019   |
| ISO 10993-10 | Biological evaluation of medical devices Part 10: Tests for skin sensitization                                                                                           | 2021              |
| ISO 10993-23 | Biological evaluation of medical devices Part 23: Tests for irritation                                                                                                   | 2021              |
| ISO 11737-1  | Sterilization of health care products — Microbiological methods Part 1: Determination of a population of microorganisms on products                                      | 2018+AMD 1:2021   |
| ISO 11138-1  | Sterilization of health care products — Biological indicators Part 1: General requirements                                                                               | 2017              |
| ISO 11135    | Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices | 2014 + AMD1: 2018 |
| ISO 11607-1  | Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems                                  | 2019 + AMD1:2023  |
| ISO 11607-2  | Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes                                        | 2019+ AMD1:2023   |
| ASTM F1980   | Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices                                                                                      | 2016              |
| FDA Guidance | Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery                                                                              | March 9, 2020     |

Based on conformance with the applicable consensus standards and consistency with FDA guidance document referenced above, the performance and safety of the Irrigation Tubing Bipolar Cord Set has been demonstrated. These results support a substantial equivalence to the predicate device (K211170).

## G. Conclusion

Based on a comparative analysis of Indications for Use and technological characteristics, along with performance testing results, the data presented in this submission support a determination of substantial equivalence between the Irrigation Tubing Bipolar Cord Set and the predicate device (K211170).