October 19, 2021

Modern Medical Equipment Manufacturing, LTD.
Philip Hung
Management Representative
Flat A, 11/F., Mai Wah Ind. Bldg., 1-7 Wah Sing Street, Kwai Chung, N.T.
Hong Kong, China

Re: K211170
Trade/Device Name: Single Use Irrigation bipolar cable
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 14, 2021
Received: September 20, 2021

Dear Philip Hung:

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)*
K211170

Device Name
Sterile Single Use Irrigation Bipolar Cable

Indications for Use *(Describe)*
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.

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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1. 510(k) Owner

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Contact person:	Philip Hung
Date of preparation:	16 October 2021

2. Device

Name of Device:	Sterile Single Use Irrigation Bipolar Cable
Trade or proprietary name:	Sterile Single Use Irrigation Bipolar Cable
Common or usual name:	Sterile Single Use Irrigation Bipolar Cord
Classification name:	Electrosurgical Cutting & Coagulation Device & Accessories
Classification number:	21 CFR 878.4400
Classification Panel:	General & Plastic Surgery
Product Code:	GEI
Class:	II

3. Predicate device

Codman Integrated Irrigation Tubing and Bipolar Cord Set with 510(k) number K052449.

4. Device description

The device is single use and is used to connect an irrigation bipolar forceps to electrosurgical generator and irrigation module for coagulation and delivering saline to the tip of forceps simultaneously.

The socket connector of the cable is to fit Codman irrigating bipolar forceps. The fixed 2-pin plug is connected to any compatible generators or the flying lead connectors are connected to Malis bipolar coagulators or any compatible generators. The tubing set of the cable can be used with the Malis CMC-II irrigation module or the Malis

irrigation module 1000.

5. Indication for use

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.

6. Substantial Equivalence

The technological characteristics and performance testing of the subject and predicate devices are substantially equivalent. The following table shows the comparisons in more detail information among the subject devices and the predicate device.

Compared Items	Proposed Device (K211170) Single Use Irrigation bipolar cable (CD933)	Predicate Device (K052449) Coeman Integrated Irrigation Tubing and Bipolar Cord Set	Comments on difference
Indication for use	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 device is intended to provide irrigation and energy simultaneously to bipolar forceps specifically designed for irrigation. They are intended for use with Codman/Malis CMC-II and the Codman/Malis CMC III I.E.C. Irrigation Modules and the Codman/Malis Bipolar Coagulators.	Same
Regulation number	21 CFR 878.4400	21 CFR 878.4400	Same
Product code	GEI	GEI	Same
OTC or prescription	For prescription use	For prescription use	Same

Energy delivery	High frequency electrical current/energy	High frequency electrical current/energy	Same
Technology	For monopolar electrosurgery	For monopolar electrosurgery	Same
Design	Combined of Irrigation tubing with bipolar cable	Combined of Irrigation tubing with bipolar cable	
Material of the components - Cable wire with plug - Tubing - Luer lock - Puncture utensil - Protector for luer and puncture utensil - Pinch clamp	 Copper wire and PVC insulation PVC PC ABS ABS PP	 Copper wire and PVC insulation PVC PC ABS LDPE/PP PP	 Same Same Same Same Similar, provide the same function Same
Rated accessory voltage	500Vp	500Vp-p	Both meets IEC safety requirements
Sterile	EO sterile	EO sterile	Same
Shelf life	3 years	3 years	Same
Electrical safety and EMC	Comply with dielectric strength in with accordance IEC60601-1, IEC60601-1-2 & IEC60601-2-2	Comply with dielectric strength in with accordance AAMI HF-18	Same
Biocompatibility	Comply with ISO10993	Comply with ISO10993	**Meet biocompatibility requirements so it does not raise any safety issue for biocompatibility**

7. Non-clinical Performance Testing Data

Validation and Verification testing was performed on device sterility in accordance with ISO 11135:2014.

The safety performance of the subject device passed all the testing according to internal requirements and international standards shown below to support the substantial equivalence of the subject device

- IEC 60601-1:2005+AMD1:2012 CSV Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- IEC60601-2-2: 2017 (Fifth Ed), 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.

- IEC60601-1-2:2014, Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests

- ISO10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

- ISO 11607-1:2019 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems

Furthermore, the packaging integrity and accelerated aging test were completed on the subject device to support the proposed shelf life.

8. Conclusion

The non-clinical testing demonstrates that the subject device, the Single Use Irrigation Bipolar Cable, is substantially equivalent as the predicate device (K052449).