November 30, 2020

Modern Medical Equipment Manufacturing, Ltd.
Jerry Cheung
Assistant Regulatory Manager
Flat A, 11/F., Mai Wah Ind. Bldg., 1-7 Wah Sing Street
Kwai Chung N.T.
Hong Kong, China

Re: K200372
Trade/Device Name: Sterile and Non-sterile Single Use Smoke Evacuation Fingerswitch, Nosecone and Smoke Evacuation System with Electrosurgical Pencil
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 10, 2020
Received: February 14, 2020

Dear Jerry Cheung:

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)*
K2000372

Device Name
Sterile and Non-sterile Single Use Smoke Evacuation Fingerswitch, Nosecone and Smoke Evacuation System with Electrosurgical Pencil

Indications for Use *(Describe)*
The device is used to conduct electrosurgical current from an electrosurgical generator to target tissue in electrosurgical procedures for monopolar cutting and coagulation, with the additional function of evacuation to facilitate the removal of surgical smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.

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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1. 510(k) Owner

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Contact person:	Mr. Jerry Cheung
Date of preparation:	26 Nov, 2020

2. Device

Name of Device:	Sterile and Non-sterile Single Use Smoke Evacuation Fingerswitch, Nosecone and Smoke Evacuation System with Electrosurgical Pencil
Trade or proprietary name:	Sterile and Non-sterile Single Use Smoke Evacuation Fingerswitch, Nosecone and Smoke Evacuation System with Electrosurgical Pencil
Common or usual name:	Sterile and Non-sterile Single Use Smoke Evacuation Pencil
Classification name:	Electrosurgical Cutting & Coagulation Device & Accessories
Classification Panel:	General & Plastic Surgery
Product Code:	GEI
Class:	II

3. Predicate device

MEDTEK PLUMEPEN Integrated Smoke Evacuation Pencil with 510(k) number K103375.

4. Device description

There are two main series of smoke evacuation pencil.

(1) Smoke Evacuation Fingerswitch (PS947)

The device includes the active handle which connects with the active electrode. The diameter of the mating part is 2.36mm+/-0.02mm. The buttons on the active handle control cutting and coagulation, the yellow side activates the cutting function and the blue side activates the coagulation function. The active handle's end is connected to an insulation cord with an active connector. The EVA tubing at the rear of the active handle then leads to a filter and pump system that facilitates the removal of harmful "surgical smoke" from the site of operation.

The device is compatible with the socket of generator accommodating the standard 3-pin active connector, the output voltage setting of generator not larger 4.5kVp, compatible cable connection of grounding pad to the generator and all smoke evacuators with an ID22mm EVA tubing connector.

In addition to these familiar features and functions, the switching controls are mounted onto an active handle that moves freely up and down the shaft of the device when the device is in vertical position (or moves freely forward and backward when the device is in horizontal position), when the switching control moves freely on the shaft, distance between the front end of the handle and the controls is reduced or increased that works like extending and retracting the suction tip on general smoke evacuation, allowing the surgeon a greater degree of control and removing the need for additional accessories to extend the length of the device when working in cavities and other areas with restrictive access. Furthermore, the electrode can be exchanged with 63.5mm, 69mm and 120mm long electrodes in diameter 2.36±0.2mm with corresponding nosecone for further extending the length of suction tip for smoke evacuation.

(2) Smoke evacuation system with electrosurgical pencil (CE809)

The device includes electrosurgical pencil with electrode and smoke evacuation handle connected with EVA tubing with ID22mm tubing connector. Electrosurgical pencil (PD646 or PD631) with 69mm long electrodes in diameter 2.36±0.2mm, can be put into the handle that functions as smoke evacuation pencil.

The device is compatible with the socket of generator accommodating the standard 3-pin active connector, the output voltage setting of generator not larger 5kVp, compatible cable connection of grounding pad to the generator and all smoke evacuators with an ID22mm EVA tubing connector.

The products, PS947 and CE809 do not have technology difference.

5. Indication for use

The device is used to conduct electrosurgical current from an electrosurgical generator to target tissue in electrosurgical procedures for monopolar cutting and coagulation, with the additional function of evacuation to facilitate the removal of surgical smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.

6. Technological characteristics

Single Use Smoke Evacuation Fingerswitch and Smoke Evacuation System with Electrosurgical Pencil integrates two technologies of electrosurgery and smoke evacuation. These two devices have substantially equivalent construction and performance as the predicate devices.

7. 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 Single Use Smoke Evacuation Fingerswitch (PS947)	Proposed Device Single Use Smoke evacuation system with electrosurgical pencil (CE809)	Predicate Device (K103375) MEDTEK PLUMEPEN Integrated Smoke Evacuation Pencil	Comments on difference
Intended use	The device is intended to be used as the active monopolar electrode in an electrosurgery generator system for cutting and coagulation, with the additional function to facilitate the removal of surgical smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system	The device is intended to be used as the active monopolar electrode in an electrosurgery generator system for cutting and coagulation, with the additional function to facilitate the removal of surgical smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system	The PLUMEPEN is designed 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.	Same

Indication for use	The device is used to conduct electrosurgical current from an electrosurgical generator to target tissue in electrosurgical procedures for monopolar cutting and coagulation, with the additional function of evacuation to facilitate the removal of surgical smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.	The device is used to conduct electrosurgical current from an electrosurgical generator to target tissue in electrosurgical procedures for monopolar cutting and coagulation, with the additional function of evacuation to facilitate the removal of surgical smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.	To remove smoke plume form the surgical site and remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the target tissue for the desired surgical effect	Same
Regulation number	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	Same
Product code	GEI	GEI	GEI	Same
OTC or prescription	For prescription use	For prescription use	For prescription use	Same
Energy delivery	High frequency electrical current/energy	High frequency electrical current/energy	High frequency electrical current/energy	Same
Technology	Monopolar electrosurgery and use of vacuum source to capture smoke	Monopolar electrosurgery and use of vacuum source to capture smoke	Monopolar electrosurgery and use of vacuum source to capture smoke	Same
Device mode	Cut and coag.	Cut and coag.	Cut and coag.	Same
Design	Smoke evacuation fingerswitch is produced from that electrosurgical pencil is integrated with smoke evacuation with switching control	Smoke evacuation system with pencil includes pencil is combined with the specified suction handle that performs as those of suction evacuation pencil.	Electrosurgical pencil is integrated with smoke evacuation with extendable suction tip A variety of length of electrode be used with	Similar construction and provide the same technology to achieve target function. Extending the suction tip and

	moving on the shaft of device in order to perform as extending or retracting suction tip. Nosecone can be added to further extend the suction tip.		extendable suction tip.	electrode is only for facilitating operation in deeper surgical site
Structure of Pencil - Housing - Cable -Nosecone / Suction tip -Suction tubing -Switching -Electrode tip style -Electrode Material - Length	 - ABS - PVC - K-resin - EVA - Push button, rocker -Blade -Stainless steel - 50mm, 63.5mm, 69 mm, and 120mm.	 - ABS - PVC - K-resin - EVA - Push button, rocker -Blade -Stainless steel - 69 mm	 - ABS - PVC - K-resin - EVA and PVC - Push button -Blade - Stainless steel -69mm or longer	 The material used and structure among the purposed and predicate devices are very similar and do not raise safety and effectiveness issues because those were tested according to IEC test and biocompatibility requirements Same function Same Same Similar, longer lengths do not affect cut and coag. performance but only facilitates the electrode tip go to deeper surgical site.

- Diameter	-2,36 mm	-2,36 mm	~2.36mm	Same
-Conductive end	-15.5mm	-15.5mm	-15.5mm	Same
- Tip width	- 2.3mm	- 2.3mm	- 2.3mm	Same
- Tip depth	~0.5mm	~0.5mm	~0.5mm	Same
- Insulation material	- PTFE Shrink Wrap	- HIPS	- HIPS	The proposed electrode passes the required tests according to ISO10993, IEC60601-1 and IEC60601-2-2 so there will not any issue for safety.
- Electrode coating	-Teflon one coat	-Teflon one coat	- Teflon one coat	Same
-Rated accessory voltage	- 4.5kVp	- 5kVp	- 5kVp	Similar, does not affect performance
Max. operation power	-300W	-300W	-300W	Same
Sterile	EO sterile SAL 10^{-6}	EO sterile SAL 10^{-6}	EO sterile SAL 10^{-6}	Same purpose, EO sterilization is validated according to *ISO 11135*
Shelf life	3 years	3 years	3 years	Same
Electrical safety	Comply with dielectric strength in with accordance ES60601-1, IEC60601-1-2 & IEC60601-2-2	Comply with dielectric strength in with accordance ES60601-1, IEC60601-1-2 & IEC60601-2-2	Comply with dielectric strength in with accordance AAMI HF-18	Same kinds of safety requirements
Biocompatibility	Comply with ISO10993	Comply with ISO10993	Comply with ISO10993	Meet to biocompatibility requirements so it does not raise

				any safety issue for biocompatibility

8. The technology different raising safety or effectiveness of the devices.
Basically, the technologies used for the proposed device and predicate device are the same including electrosurgical monopolar cutting and coagulation, and smoke evacuation, only a little difference on suction tip mechanism that will not raise any additional safety issue.

9. Non-clinical Performance Testing Data
Validation and Verification testing was performed on device sterility in accordance with ISO 11135:2014.

Performance Testing included bench testing on the subject device and predicate devices by using porcine tissue: kidney, liver, muscle for both Cut mode and Coagulation mode in accordance with the Premarket Notification (510(k) Submissions for Electrosurgical Devices for General Surgery Guidance for Industry and Food and Drug Administration Staff, Document issued on August 15, 2016, the evaluation of the thermal effects on the tissues and measurement of the thermal zone sizes are proved that the subject device and the predicate device are equivalent in the performance.

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

- ANSI/AMMI ES60601-1:2005/(R)2012 + A1:2012, C1:2009/(R)2012 + A2:2010/(R)2012, 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.

10. Conclusion

Based on comparing technological characteristic and performance testing data, the subject device, Single Use Smoke Evacuation Fingerswitch and Single Use Smoke Evacuation System with Electrosurgical Pencil are substantially equivalent to predicate device (K103375).