January 28, 2021

Shining World Health Care Co., Ltd.
Mrs. Anita Chen
Regulatory Advisor
No.22, Ln. 116, Wugong 2nd Rd., Wugu Dist
New Taipei City, Taiwan 248
Taiwan (R.O.C)

Re: K213317

Trade/Device Name: ShinEvac Smoke Evacuation Pencil
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 16, 2021
Received: October 4, 2021

Dear Mrs. Chen:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213317

Device Name
ShinEvac® Smoke Evacuation Pencil

Indications for Use *(Describe)*
The ShinEvac® Smoke Evacuation Pencil 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 and electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.

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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Section 5 510(k) Summary

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted as part of the Premarket Notification in compliance with requirements of CFR Part 807, Subpart E and Section 807.92

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The assigned 510(k) Number: K213317

1.	Manufacturer	Shining World Health Care Co., Ltd.
	Address	No.22, Ln. 116, Wugong 2nd Rd., Wugu Dist., New Taipei City 248, Taiwan (R.O.C.). TEL: +886-2-22900966 FAX: +886-2-22903966
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	Phone:	+886-2-22900966
	E-mail:	Anita9104303@gmail.com
	Date Prepared	January 21, 2022

2	Device Name	
	Proprietary Name:	ShinEvac® Smoke Evacuation Pencil
	Model Name	Classic, AIO
	Model No.	SW12200-APBCSE36 SW12200-APBCSE36G SW12200-APBCSE56 SW12200-APBCSE56G SW12200-APBCSB36 SW12200-APBCSB56
	Regulation Number:	21 CFR 878.4400
	Regulation Name:	Electrosurgical cutting and coagulation device and

		accessories
	Regulatory Class:	Class II
	Product Code:	GEI

3	Predicate Device Name	PLUMEPEN® Integrated Smoke Evacuation Pencil
	510(k) number	K103375
	Trade/Device Name:	PLUMEPEN
	Regulation Number:	21 CFR 878.4400
	Regulation Name:	Electrosurgical cutting and coagulation device and accessories
	Regulatory Class:	Class II
	Product Code:	GEI

4	Device Description	The ShinEvac® Smoke Evacuation Pencil, model: SW12200-APBCSE36, SW12200-APBCSE36G, SW12200-APBCSE56, SW12200-APBCSE56G, SW12200-APBCSB36 and SW12200-APBCSB56 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. Electro surgical Pencil is one of accessories of HF Electro Surgical Unit generates frequency from 300~600KHz for coagulation and cutting function, power up to 80W and 120W respectively. It is connected with cable conducting electro energy from unit and is holding a detachable tip electrode for the

		electrosurgery. This device is compatible with the Ø 2.38mm tip electrode and the maximum voltage is 4.5 KV peak. Th is device can remove surgical smoke when connected to a smoke evacuator.
5.	Intended Use:	The ShinEvac® Smoke Evacuation Pencil 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 and electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.
6.	Technological Characteristics and Substantial Equivalence Comparison with Predicate:	A comparison of the device features, intended use, and other information demonstrates that the ShinEvac® Smoke Evacuation Pencil is substantially equivalent to the predicate device as summarized in *Table 1*. The differences raise no new question of safety and effectiveness.

Table 1

Manufacturer	Shining World Health Care Co., Ltd.	MEDTEK DEVICES, INC., dba Buffalo Filter
Device name	Subject Device ShinEvac® Smoke Evacuation Pencil	Predicate device PLUMEPEN® INTEGRATED SMOKE EVACUATION PENCIL
510(k) Number	K213317	K103375
Intended Use	The ShinEvac® Smoke Evacuation Pencil 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 and electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.	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 and electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.
Regulation name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories
Rag Number	21 CFR 878.4400	21 CFR 878.4400
Product Code	GEI	GEI
Class	II	II
Energy Source	Electrosurgical Generator	Electrosurgical Generator
Sterility	Sterile by Ethylene Oxide (EO)	Sterile by Ethylene Oxide (EO)
Technical Design	Pencil body with removable evacuation tube	Pencil body with removable evacuation tube

Patient Contact	Invasive tissue contact		Invasive tissue contact
Electrode	Stainless/non-stick		Stainless/non-stick
Patient Population	General population		General population
Prescription or OTC	Prescription		Prescription
Single Use	Yes		Yes
Model	Classic	AIO	NA
Design	Pencil body with removable evacuation tube	Extendable suction tube	Pencil body with removable evacuation tube
Specification	Disposable with 65mm electrode, 3M/5M cable, and holster. Cut and Coagulation button	Disposable with 70mm electrode, 3M/5M cable, and holster. Cut and Coagulation button	Disposable with 70mm electrode, 3M cable, and holster. Cut and Coagulation button

7. Performance and Safety Test

a. Performance Testing

- Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery Guidance for Industry and Food and Drug Administration Staff, 2020.
- Animal study and clinical investigation

The Animal study was evaluated the safety and performance of the device in three different tissues under worst case scenarios. The outputs of energy were applied with low, moderate, and high watts in liver, kidney and muscle to test of the cutting performance and also evaluated the safety from tissue temperature, tissue cooling time and the extent of tissues' thermal damage.

- Clinical investigation isn't required for these devices.

b. Safety Test:

-IEC 60601-1:2005+COPR.1:2006+COPR.2:2007+A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility requirements and tests
- IEC 60601-2-2:2017, 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 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

c. Biocompatibility testing

The biocompatibility evaluation and testing of the ShinEvac® Smoke Evacuation Pencilwas conducted in accordance with the following standards and guidance, as recognized by the FDA:

-FDA Guidance - Use of International Standard ISO- 10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing".
-ISO 10993-5, Biological evaluation of medical devices- Part 5: Tests for in vitro

cytotoxicity

-ISO 10993-10, Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization

-ISO 10993-11, Biological evaluation of medical devices Part 11: Tests for systemic toxicity

-USP 42/NF37:2019 <151> Pharmacopeia US : Pyrogen Test

d. Sterilization Validation

- ISO 11135:2014 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

8. Conclusion

Based on the intended use and/or indications for use, technological characteristics, performance testing and comparison to the predicate device, the ShinEvac® Smoke Evacuation Pencil is substantially equivalent to the predicate device and raises no new questions of safety or effectiveness.