Ningbo Shun Ye Medical Company, Ltd.
Mr. Frank Yu
Official Correspondent
No.5 Industry Road, Zhangqi Industry Zone, Cixi
Ningbo City , Zhejiang 315313
China

June 27, 2022

Re: K213786
Trade/Device Name: Single use electrosurgical pencil with electrode
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 19, 2022
Received: April 28, 2022

Dear Mr.Yu:

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,

for

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)*
K213786

Device Name
single use electrosurgical pencil with electrode

Indications for Use *(Describe)*
The device is to be used in combination with a standard electrosurgical generator to cut and coagulate soft tissue by means of high frequency electrical current during an electrosurgical procedure.

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

(Submitted As Required per 21 CFR 807.92)

I. GENERAL INFORMATION

Submitter Name:	Ningbo Shun Ye Medical Company, Ltd.
Establishment Registration Number:	3007593903
Submitter Address:	No. 5 Industry Road, Zhangqi Industry Zone, Cixi, Ningbo City 315313 Zhejiang, China
Submitter Telephone Number:	011 - 86 - 574 - 6377 - 8018
Submitter FAX Number:	011 - 86 - 574 - 6377 - 8028
Contact Person:	Frank Yu General Manager
Date Prepared:	October 2021

II. DEVICE IDENTIFICATION

Proprietary Name:	Single use electrosurgical pencil with non-coated and non-stick electrode;
Common Name:	**Single use electrosurgical pencil with electrode**
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Classification:	21CFR 878.4400; Class II; Product Code GEI

III. PREDICATE DEVICE

Table 1: Predicate device information

Predicate device	510k number	510k holder	Clearance date
Single Use Electrosurgical pencil with non-coated and non-stick electrode	K192542	Modern Medical Equipment Manufacturing Limited	16-Jun-20

IV. DEVICE DESCRIPTION

The **Single use electrosurgical pencil with electrode** is a monopolar active device which consists of a conductive electrode tip, an insulated shaft and a conductive post. It directs high frequency alternating current to heat target tissue thereby bringing about cutting and coagulation during surgical procedures.

The electrosurgical pencil handpiece consists of a plastic handle, electrical cable and a plug. The switching modes are for "CUT" and "COAG" function. A socket in front of the pencil casing is used to allow the insertion of an electrode.

The electrosurgical pencil handpiece is available in 3 models, differing only in their button configuration: Push Button Electrosurgical Pencil (Model #: GDSA), Electrosurgical Rocker Pencil (Model #: GDSB), and Electrosurgical Foot Control Pencil (Model #: GDJA).

The electrode consists of a conductive electrode tip, an insulated shaft and a conductive post. The electrode tip may be blade, ball, needle and dermal tip. The electrode tip is either coated or non-coated. There may or may not be a heat shrink attached. There are 47 different types of electrodes.

The model number of each subjective device "**Single use electrosurgical pencil with electrode**" consists of two parts: the first four letters representing model number of the pencil, and the second part representing model number of the electrode. For example, model number: GDSA-DA-C66 is for *Push Button Electrosurgical Pencil with Standard Blade 2.6"*. There are 141 different combinations of pencil and electrode.

The diameter of the conductive post is 2.36mm. The pencil with electrode attached is to be connected to a general high frequency electrosurgical generator by means of the electrical cable and is used in conjunction with a patient grounding pad during an electrosurgical procedure.

The switching method of this electrosurgical pencil may be push button, rocker switch or foot switch. The cable length of the electrosurgical pencil will be around 3m to 5m with 3-pins plug or 1-pin plug.

The **single use electrosurgical pencil with electrode** has the same intended use and energy type as the predicate device. There are no technological differences, no changes to the principle of operation or the method of application.

V. INTENDED USE/INDICATIONS

The monopolar electrosurgical pencil with electrode is used to deliver high frequency current to target tissue for cutting and coagulation.

This is identical to the intended use/indications of the predicate device.

VI. PROPOSED/PREDICATE DEVICE COMPARISON

Compared items	Proposed device (K213786) Single use electrosurgical pencil and non-coated and non-stick electrode	Predicate device (K192542) Single use electrosurgical pencil and non-coated and non-stick electrode	Comments
Intended use	The monopolar electrosurgical pencil with electrode is used to deliver high frequency current to target tissue for cutting and coagulation	The monopolar electrosurgical pencil with electrode is used to deliver high frequency current to target tissue for cutting and coagulation	same
Indication for use	To cut and coagulate soft tissue by means of high frequency electrical current during an electrosurgical procedure.	To cut and coagulate soft tissue by means of high frequency electrical current during an electrosurgical procedure.	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
Monopolar or bipolar	Monopolar	Monopolar	same
Generator Compatibility	To be used with a standard electrosurgical generator with footswitch control and a standardreturn electrode connection	To be used with a standard electrosurgical generator withfootswitch control and a standard return electrode connection	same
Design	Monopolar electrosurgical pencil for cutting and coagulation and with different electrode tips as blade, needle, and ball	Monopolar electrosurgical pencil for cutting and coagulation and with different electrode tips as blade, needle, and ball	same target purpose
User Interface	Footswitch/Hand	Footswitch/Hand	same
Structure Pencil - Housing - Cable - Switching	 ABS PVC Push button, rocker switch & footcontrol	 ABS PVC Push button, rocker switch &foot control	The material used and structure among the proposed 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
Electrode - Material	 Stainless steel	 Stainless steel	 Same
- Length	66mm, 70mm, 101mm,152mm (blade) 65mm (angled blade)	69 mm, 102mm, 152mm (blade & needle)	Similar, length of electrode does not raise any safety and performance issues

	72mm, 101mm, 152mm (needle) 60mm, 66mm (angled needle) 60mm (dermal tip) 49mm, 50mm, 51mm, 132mm,133mm,134mm(ball)	69-71mm, 105-107mm,135-137mm (ball)	
- Diameter	~2.36mm	~2.36mm	Same
- Insulation material	Kynar Shrink Wrap and/or ABS/HIPS overmold	Polyolefin Shrink Wrap and/or PTFE Shrink Wrap, Or ABS/HIPS overmold	Similar. The proposed electrode passes the required tests according to IEC60601-1 and IEC60601-2-2 so there are not any issues for safety.
- Electrode Tip Configuration	Blade, Needle, Ball	Blade, Needle, Ball	Same
- Electrode coating	Teflon coat	Teflon coat	Same
- Rated accessory voltage	4kVp	4kVp, 5kVp	Similar. The proposed electrode passes the required tests according to IEC60601-1 and IEC60601-2-2 so there are not any issues for safety and performance.
Sterilization	EO sterile	EO sterile	Same. EO sterilization is validated according to ISO 11135.

Shelf life	3 years	3 years	Same
Electrical safety	Comply with dielectric strength in accordance with IEC60601-1, IEC60601-1-2 & IEC60601-2-2	Comply with dielectric strength in accordance with IEC60601-1, IEC60601-1-2 & IEC60601-2-2	same
Biocompatibility	Comply with ISO10993	Comply with ISO10993	Same

VII. SAFETY/PERFORMANCE TESTING

The following performance data are provided in support of substantial equivalence determination.

Performance testing

Performance testing was conducted for the proposed device in accordance with requirements of FDA's Guidance: **Guidance for Industry and FDA Staff: Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery (issued on March 9, 2020).**

A study was performed to compare the penetrating thermal tissue effects of the Shun Ye Medical Electrosurgical Pencil to MMEQ Electrosurgical Pencil. Test specimens used are listed as follows:

- Porcine Liver
- Porcine Kidney
- Porcine Muscle tissues

Biocompatibility testing

The biocompatibility evaluation for the **single use electrosurgical pencil with electrode** was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Skin sensitization
- Intracutaneous reactivity test
- Acute systemic toxicity
- Pyrogen Testing

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the **single use electrosurgical pencil with electrode**. The product complies with the IEC 60601-1 and IEC60601-2-2 standards for safety, IEC 60601-1-2 standard for EMC.

The **single use electrosurgical pencil with electrode** was designed in accordance with the following standards:

International Standard	Description
IEC 60601-1, Edition 3.1	Medical Electrical Equipment - Part 1: General Requirements for Safety
IEC 60601-1-2 Edition 4.0 2014-02	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-2-2 Edition 6.0 2017-03	Particular requirements for the safety of high frequency surgical equipment
ISO 11135-1: 2007	Sterilization of Healthcare Products – Ethylene Oxide – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.
ISO 10993-7:2008	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Residuals
ISO 10993-12：2012	Biological evaluation of medical devices — Part12: Sample preparation and reference materials
ISO 10993-2:2006	Biological evaluation of medical devices Part 2: Animal welfare requirements
ISO 10993-11：2017	Biological evaluation of medical devices Part 11: Tests for systemic toxicity
ISO 10993-5:2009	Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-1:2018	Biological Evaluation of Medical Devices Part 1: Evaluation and Testing with a Risk Management Process

VIII. CONCLUSION

There is no difference between the **Single use electrosurgical pencil with electrode** and the predicate device in terms of intended use, principle of operation, and the technology used for device performance. There is no new technology and no difference that would raise new or different questions of safety or efficacy. Therefore, we conclude that the devices are substantially equivalent.