April 7, 2026

Zhejiang shuyou Surgical Instrument Co., Ltd.
Jialong Wu
Quality Management Representative
Zhejiang shuyou Surgical Instrument Co., Ltd.
3689#, E. Yangguang Ave., Dipu St. Anji, Huzhou, Xhejiang 313300 CHN

Re: K260466
Trade/Device Name: Multifunctional Operational Dissectors (Electrosurgical Pencils);Multifunctional Operational Dissectors (Disposable Electrode)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 24, 2026
Received: February 12, 2026

Dear Jialong Wu:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JAMES H. JANG -S
Digitally signed by JAMES H. JANG -S
Date: 2026.04.07 22:33:01 -04'00'

James Jang, Ph.D.
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260466

Please provide the device trade name(s).

Multifunctional Operational Dissectors (Electrosurgical Pencils);
Multifunctional Operational Dissectors (Disposable Electrode)

Please provide your Indications for Use below.

Electrosurgical Pencil and Accessories designed for general electrosurgical applications, including cutting and coagulation, illumination and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The electrosurgical 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.

Electrosurgical Electrode Accessories designed for general electrosurgical applications, including cutting and coagulation. The electrosurgical electrode 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K260466 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K260466

1. Date of Preparation: 04/02/2026

2. Sponsor Identification

Zhejiang shuyou Surgical Instrument Co., Ltd.
3689#, East Yangguang Avenue, Dipu Street Anji Huzhou City, Zhejiang Province China

Establishment Registration Number: Not registered

Contact Person: Jialong Wu
Position: Quality Management Representative
Tel: +86-13735120013
Email: wujialong@shuyou-china.com

3. Identification of Proposed Device

Trade Name: Multifunctional Operational Dissectors (Electrosurgical Pencils)
Multifunctional Operational Dissectors (Disposable Electrode)
Common Name: Electrosurgical Smoke Evacuation Pencil

Regulatory Information
Classification Name: Electrosurgical, cutting & coagulation & accessories
Classification: II,
Product Code: GEI,
Regulation Number: 21 CFR 878.4400,
Review Panel: General & Plastic Surgery.

Indications for Use
Electrosurgical Pencil and Accessories designed for general electrosurgical applications, including cutting and coagulation, illumination and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The electrosurgical 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.

Electrosurgical Electrode Accessories designed for general electrosurgical applications, including cutting and coagulation. The electrosurgical electrode 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.

Device Description
The electrosurgical pencil mainly consists of electrode, functional tube, insulating layer, plastic handle, manual button switch, cable, plug, Teflon material, suction tube joint, three-way valve. There are four main types of electrosurgical pencil, including SY-I, SY-II, SY-III and SY-IV. The design of the four types of electrosurgical pencil is different, and each type of electrosurgical pencil has differences in size and shape.

The disposable electrode is composed of electrode shaft, insulation layer, or plastic handle. There are six main types of disposable electrode, including ordinary electrode, tungsten needle electrode, tungsten wire electrode, silicone electrode, endoscopic electrode and orthopedic electrode. The size and shape of the six types of disposable electrode is different.

4. Identification of Predicate Devices and Reference Device

Predicate Device
510K Number: K230547
Trade Name: PlumePen (Elite, Pro and Ultra) Surgical Smoke Evacuation Pencil

Reference Device
510K Number: K192542
Trade Name: Single Use Electrosurgical pencil with non-coated and non-stick electrode

5. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-7:2008 Biological Evaluation Of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals
- ISO 10993-5:2009 Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2021 Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization
- ISO 10993-11:2017 Biological Evaluation of Medical Devices-Part 11: Tests for systemic toxicity
- ISO 10993-23:2021
- USP<151> Pyrogen Test

- ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F88/F88M-23 Standard test method for seal strength of flexible barrier materials
- ASTM F1929-23 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems
- IEC 60601-1:2005, AMD1: 2012, AMD2: 2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- 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
- IEC TR 60601-4-2: 2024 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 60601-1-2: 2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- USP<85> Bacterial Endotoxins Test

The performance testing conducted on subject device and predicate device are listed below. All the test results demonstrate proposed device meet the requirements of its pre-defined acceptance criteria and intended uses.

- Appearance test
- Dimension test
- Conductivity test
- Detachable active electrode insert/pull force test
- Reliability testing of power cord
- High-frequency leakage current testing
- Dominant-frequency high-voltage
- High-frequency high-voltage test
- Corrosion resistance test

Thermal Effects on Tissue

In accordance with the nonbinding FDA guidance on “Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery”, part XI-E, the thermal effects on animal tissue of our device was compared with the predicate device K230547 Ex-vivo kidney, liver, and muscle tissues were used and the thermal damage zone sizes were compared for width, and depth. These tests showed that the thermal effects of proposed device are virtually identical to those shown in the predicate device.

The proposed device sterilization process using Ethylene Oxide (EO) has been validated in accordance with ISO 11135:2014 to achieve a sterility assurance level (SAL) of 10^{-6}. EO and Ethylene Chlorohydrin (ECH) residuals were below the limits specified in ISO 10993-7:2008. Bacterial Endotoxin Levels were below the level of 20 EU/device in accordance with USP <85>. Both baseline and accelerated shelf life testing were conducted demonstrating the device will perform as intended to support the proposed 3-year shelf-life.

- Package Integrity Test – after environmental conditioning, simulated transportation testing in accordance to ASTM D4169-22 on final, packaged, and sterile device.
- Sterile Barrier Packaging performed on the proposed device:
  - Visual Inspection per ASTM F1886/F1886M-16
  - Seal Strength per ASTM F88/F88-21
  - Dye Penetration per ASTM F1929-15
- Shelf-life of 5 years is validated using FDA recognized standard ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

The biocompatibility evaluations were conducted in accordance with the 2020 FDA Guidance document Use of International Standard ISO-10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The cytotoxicity, sensitization, intracutaneous irritation, system toxicity, pyrogen and hemolysis tests were performed to demonstrate the biocompatibility of the device.

Tests on Electromagnetic Compatibility and Electrical Safety were performed in accordance with requirements per IEC 60601-1:2005, AMD1: 2012, AMD2: 2020, IEC 60601-1-2: 2014+A1:2020 and IEC TR 60601-4-2: 2024, and in particular we also conducted tests on high frequency surgical equipment accessories per IEC 60601-2-2: 2017.

6. Clinical Test Conclusion

No clinical study is included in this submission.

7. Substantially Equivalent (SE) Comparison

Table 1. General Comparison

Item	Proposed Device	Predicate Device K230547	Reference Device K192542	Remark
Device Name	Multifunctional Operational Dissectors (Electrosurgical Pencils) Multifunctional Operational Dissectors (Disposable Electrode)	PlumePen (Elite, Pro and Ultra) Surgical Smoke Evacuation Pencil	Single Use Electrosurgical pencil with non-coated and non-stick electrode;	/
Product Code	GEI	GEI	GEI	Same
Regulation No.	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	Same
Class	II	II	II	Same
Indications for Use	Electrosurgical Pencil and Accessories designed for general electrosurgical applications, including cutting and coagulation, illumination and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The electrosurgical 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. Electrosurgical Electrode Accessories designed for general electrosurgical applications, including cutting and coagulation. The electrosurgical electrode enables the operator to remotely conduct an electrosurgical current from the output connector of an	The PlumePen® Elite, PlumePen® Ultra, and PlumePen® Pro 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. Indicated for use to remove smoke plume from the surgical site and to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the target tissue for the desired surgical effect.	The devices are used to cut and coagulate soft tissue by means of high frequency electrical current during an electrosurgical procedure.	Similar

	electrosurgical unit to the operative site for the desired surgical effect.			
Prescription or OTC	Prescription	Prescription	Prescription	Same
Energy delivery	High frequency electrical current/energy	High frequency electrical current/energy	High frequency electrical current/energy	Same
Polarity	Monopolar	Monopolar	Monopolar	Same
Rated Voltage	3kV	5kVpk	4kVp, 5kVp	Different
Shelf-life	5 years	3 years	3 years	Different
Single use/ reusable	Single patients use device	Single patients use device	Single patients use device	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Design	Monopolar electrosurgical pencil for cutting, coagulation, illumination and removing smoke, and with different electrode. The electrode tips as blade, needle, ball, straight, curved, circular, square, B-shape, triangular, shovel, hook and serrated shape.	Monopolar electrosurgical pencil for cutting, coagulation and removing smoke, and with different blade electrode tips	Monopolar electrosurgical pencil for cutting and coagulation, and with different electrode tips as blade, needle and ball	Similar
Switching method of electrosurgical pencil	Push button or foot switch	Unknown	Push button, rocker switch or foot switch	Same
Cable of the electrosurgical pencil	2.5~3.2m with 3-pins plug or 1-pin plug	Unknown	3~5m with 3-pins plug or 1-pin plug	Similar
Electrode length	100~330mm	Unknown	69mm~152mm	Similar
Electrode diameter	2.36mm	Unknown	2.36mm	Same
Electrical Safety	IEC 60601-1	IEC 60601-1	IEC 60601-1	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	Same
Particular requirements	IEC 60601-2-2	IEC 60601-2-2	IEC 60601-2-2	Same
Biocompatibility				
Cytotoxicity	No cytotoxicity	Conform with ISO 10993 standards	Conform with ISO 10993 standards	Same
Intracutaneous	No intracutaneous reactivity			

Reactivity				
Sensitization	No sensitization			
Acute System Toxicity	No acute system Toxicity			
Pyrogen	No pyrogen			
Hemolysis	No hemolysis			
Patient-contact component and material	Electrosurgical Pencil: stainless steel, Teflon coating, PE heat shrink tubing, white powder, ABS, PC, POM, grey powder, tungsten, PTFE heat shrink tubing, PVDF heat shrink tubing, blue powder, silicone coating Disposable Electrode: stainless steel, Teflon coating PTFE heat shrink tubing, PE heat shrink tubing, blue power, ABS, PVDF heat shrink tubing, tungsten, yellow power, silicone coating, ceramic, epoxy resin spray powder	Unknown	Stainless steel, Teflon coating, ABS, PVC, polyolefin shrink, wrap and/or PTFE shrink wrap or ABS/HIPS overmold	Different
Sterilization				
Sterile/non-sterile	Sterile	Sterile	Sterile	Same
Method	EO sterilized	EO sterilized	EO sterilized	Same
SAL	10^{-6}	10^{-6}	10^{-6}	Same

Similar - Indications for Use

The proposed electrosurgical pencils and predicate device share the same intended use and share the same functions, including cutting, coagulation, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The proposed disposable electrode, as a component of the electrosurgical pencils, has the functions of cutting and coagulation. These two functions are covered by the predicate device.

And both of these devices enable the operator remotely to conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect. The principles and functions of the proposed devices and predicate devices are the same, except for slight differences in the textual descriptions. Furthermore, a comparison test was conducted between the proposed device and predicate device. The test results showed that there was no significant difference between the performance of the proposed device and that of the predicate device. Therefore, this difference will not

affect the safety and effectiveness of the proposed device.

Different - Rated Voltage

The rated voltage of the proposed electrosurgical pencil is different from the predicate devices 1. However, the rated voltage of proposed electrosurgical pencil complies with IEC 60601-1 standard, the difference in rated voltage is just the difference in device design. Therefore, this difference on rated voltage is considered not to affect the safety and effectiveness of the proposed device.

Different- Shelf-life

The shelf-life of the proposed electrosurgical pencil is different from the predicate devices 1. However, the proposed device underwent a shelf-life test, and all the test results of the aged devices met the acceptance criteria. Therefore, this difference on rated voltage is considered not to affect the safety and effectiveness of the proposed device.

Similar – Design

The proposed device is the same as the predicate device, both monopolar electrosurgical pencil different electrodes that can perform cutting, coagulation and smoke removal functions. However, the electrodes in the proposed device come in various shapes to be used in different medical situations. Electrodes of different shapes were also subjected to performance tests to verify the performance of the electrodes. Both the proposed device and the predicate device underwent comparative tests, and the test results indicated that there was no significant difference in performance between the two devices. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Similar – Cable of the electrosurgical pencil

The lengths of the cables for the proposed device and predicate device are slightly different, but the cable lengths do not affect the cutting and coagulation functions of the electrodes. Moreover, both the proposed device and the reference product are cables with 3-pins plug or 1-pin plug. Additionally, both the proposed device and the predicate device underwent comparative tests, and the test results indicated that there was no significant difference in performance between the two devices. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Similar – Electrode length

The electrode length of the predicate device is unknown, but the electrode length of the proposed device is similar to that of the reference device. Both proposed device and reference device have multiple different electrode lengths. The proposed device offers more electrode lengths for doctors to make appropriate choices based on the patient's condition. Additionally, both the proposed device and the predicate device underwent comparative tests, and the test results indicated that there was no significant difference in performance between the two devices. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Different - Material

The patient-conduct component and material of the predicated device 1 are unknown. However, the biocompatibility tests were conducted on the proposed device and the test result showed that the proposed device does not raise the adverse effect on the material. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

8. Substantially Equivalent (SE) Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and perform as well as or better than the legally marketed predicate device K230547 and reference device K192542.