Erbe Elektromedizin GmbH
Matthias Kollek
Regulatory Affairs Specialist
Waldhoernlestrasse 17
Tuebingen, 72072
Germany

August 29, 2025

Re: K251108
Trade/Device Name: Erbe ESU Model VIO® 3n with Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 1, 2025
Received: August 1, 2025

Dear Matthias Kollek:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2025.08.29 10:33:44 -04'00'

Colin Kejing Chen
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.	K251108

Please provide the device trade name(s).

Erbe ESU Model VIO® 3n with Accessories

Please provide your Indications for Use below.

The Erbe Electrosurgical Unit (ESU/Generator) model VIO 3n with instruments and accessories is intended to deliver high frequency (HF) electrical current for the cutting and/or coagulation of tissue.

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

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

510(k) SUMMARY

Applicant

Erbe Elektromedizin GmbH
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72072 Tuebingen
Germany
Tel: 0049-7071-755-0
Fax: 0049-7071-755-179

Contact Person

Dr. Matthias Kollek
Regulatory Affairs Specialist
E-Mail: Matthias.Kollek@erbe-med.com

Date Prepared

April 7, 2025

Device Information

Trade/Proprietary Name:	Erbe ESU Model VIO® 3n with Accessories
Common Name:	Electrosurgical system generator
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Regulation Number:	21 CFR 878.4400
Class:	II
Product Code:	GEI

Legally Marketed Predicate Devices

Primary

Erbe ESU Model VIO 3 with Accessories - K240932

Secondary

Erbe ESU Model VIO 300 D with Accessories - K083452

Device Description

The Erbe ESU Model VIO® 3n is an electrosurgical unit (ESU) that delivers high-frequency (HF) electrical current for cutting and/or coagulation of tissue. The unit can be mounted/secured to a cart/system carrier or on a ceiling mount. Different footswitches are available for activating the ESU. The ESU VIO® 3n has several clearly defined monopolar and bipolar cutting and coagulation modes with different electrical waveforms and electrical parameters that are programmed with defined effect levels. Each effect level corresponds to a defined maximum power output and a voltage limitation. In combination with the compatible argon plasma coagulation unit APC 3 (K191234), it offers monopolar modes for argon plasma coagulation and argon-supported modes. The ESU has a touchscreen monitor that provides the user with an onscreen tutorial as well as settings and operational information. It also provides a small number of physical controls, such as the power switch, instrument sockets and a neutral electrode receptacle. Connections for the central power supply, for footswitches, for potential equalization of the operating theatre and Erbe Communication Bus (ECB) connections to other Erbe modules are located at the rear. The ESU emits sounds when instruments are activated, and messages are signaled. The actual application is carried out using compatible electrosurgical instruments that are connected to the generator. The VIO® 3n can be combined with matching Erbe devices and modules, instruments, and accessories. To address various clinical needs, the ESU is available in 5 different configurations which are called “Fire”, “Metal”, “Stone”, “Water” and “Timber”. Whereas the configuration “Fire” includes all available modes and functionalities, the other configurations only offer a reduced number of modes and functionalities.

Indications for Use

The Erbe Electrosurgical Unit (ESU/Generator) model VIO 3n with instruments and accessories is intended to deliver high frequency (HF) electrical current for the cutting and/or coagulation of tissue.

Comparison of Technological Characteristics

Characteristics	Subject Device Erbe ESU Model VIO 3n with Accessories	Primary Predicate Device Erbe ESU Model VIO 3 with Accessories (K240932)	Secondary Predicate Device Erbe Model VIO 300 D with Accessories (K083452)	Discussion
Manufacturer	Erbe Elektromedizin GmbH (Germany)	Erbe Elektromedizin GmbH (Germany)	Erbe Elektromedizin GmbH (Germany)	N/A
Trade/ Proprietary Name	Erbe ESU Model VIO® 3n	Erbe ESU Model VIO® 3	Erbe ESU Model VIO 300 D	N/A
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories	Electrosurgical, Cutting & Coagulation & Accessories	Electrosurgical, Cutting & Coagulation & Accessories	Same
Classification Regulation	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	Same
Product Code	GEI	GEI	GEI	Same
Device Class	II	II	II	Same
Indications for Use	The Erbe Electrosurgical Unit (ESU/Generator) model VIO 3n with instruments and accessories is intended to deliver high frequency (HF) electrical current for the cutting and/or coagulation of tissue.	The Erbe electrosurgical unit (ESU/Generator) model VIO 3 with instruments and accessories is intended to deliver high frequency (HF) electrical current for the cutting and/or coagulation of tissue, including ablation.	The ERBE ESU Model VIO 300 D with Accessories is intended to deliver High Frequency (HF) electrical current for the cutting and/or coagulation of tissue.	Same
Prescription or OTC	Prescription	Prescription	Prescription	Same
Dimensions	Width x Height x Depth 410 x 165 x 381 mm	Width x Height x Depth 415 x 215 x 375 mm	Width x Height x Depth 410 x 165 x 380 mm	Similar
Weight	8 kg	12 kg	9.5 kg	Similar
Energy	Monopolar and Bipolar HF electrical current	Monopolar and Bipolar HF electrical current	Monopolar and Bipolar HF electrical current	Same
Technical/ Performance Data	Mains voltage 100 V - 240 V AC (±10%)	Mains voltage 100 - 240 V AC (±10%)	Mains voltage 100 - 240 V AC (±10%)	Same
	Mains current max. 6.3A	Mains current max. 6.3A	Mains current max. 8 A // 4 A	Same as primary predicate device

Characteristics	Subject Device Erbe ESU Model VIO 3n with Accessories	Primary Predicate Device Erbe ESU Model VIO 3 with Accessories (K240932)	Secondary Predicate Device Erbe Model VIO 300 D with Accessories (K083452)	Discussion
	Mains frequency 50 Hz / 60 Hz	Mains frequency 50 Hz / 60 Hz	Mains frequency 50 Hz / 60 Hz	Same
	Frequency 350 kHz	Frequency 350 kHz	Frequency 350 kHz	Same
	Activation via footswitch or finger switch (depending on instrument)	Activation via footswitch or finger switch (depending on instrument)	Activation via footswitch or finger switch (depending on instrument)	Same
	Maximum Power Output 360 watts	Maximum Power Output 400 watts	Maximum Power Output 400 watts	Lower maximum power output
Output Modules/ Receptacles	Up to 3 HF instrument sockets 1 Neutral electrode socket 2 Footswitch sockets	4 HF instrument sockets 1 Neutral electrode socket 2 Footswitch sockets	3 HF instrument sockets 1 Neutral electrode socket 2 Footswitch sockets	Same as secondary predicate device
External interfaces	2 ECB sockets Service interface (special USB slot)	2 ECB sockets	1 ECB socket	Additional service interface
User Interface	Touch screen	Touch screen	No touch screen	Same as primary predicate device
Software Version	V1.1.0	V1.4.5 V2.0.0	V2.7.2	Different Software
Configurations	5 configurations	1 configuration	1 configuration	Different configurations

The subject device and the predicate devices have the same intended use, fundamental technology, operating principle and supply the same energy.

Differences include the device software, external interfaces, available modes and maximum power output. In addition, the subject device is available in different configurations.
To show safety and effectiveness of the subject device and to substantiate substantial equivalence, performance testing applicable to the subject device was completed to ensure it performs as intended per the product specifications and requirements in accordance with the intended use.
The non-clinical testing described below shows that the different technological characteristics do not negatively affect the safety and effectiveness of the subject device.

Non-clinical performance testing

Verification/validation activities from non-clinical testing as described below demonstrate that the differences do not raise any new issues of safety or effectiveness of the subject device compared to the predicate devices.

Functional testing and design controls to verify both safety and performance of the subject device was performed in compliance with 21 CFR 820.30 to ensure that the subject device performs as intended and meets design specifications.

Side-by-side tissue testing was performed in compliance with FDA Guidance "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery", to validate the cutting and coagulation mode performance compared to the predicate device(s).

Electromagnetic compatibility (EMC) was tested in compliance with IEC 60601-1-2 and FDA Guidance "Electromagnetic Compatibility (EMC) of Medical Devices".

Electrical safety of the subject device was tested in compliance with IEC 60601-1 and IEC 60601-2-2, as applicable.

Software verification was provided for an enhanced documentation level in compliance with IEC 62304 and FDA Guidance "Content of Premarket Submissions for Device Software Functions".

Cybersecurity was tested and assessed according to FDA Guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions".

Conclusion

The subject device and the predicate devices have the same intended use, fundamental technology, operating principle and supply the same energy.
The subject device was tested as described above to demonstrate reasonable assurance of safety and effectiveness. The subject device does not raise new or different questions of safety and effectiveness, and the subject device is substantially equivalent to the predicate device(s).