December 18, 2025

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

Re: K253915
Trade/Device Name: MOVIVA® Hybrid Ablation Probe
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, FQH
Dated: December 8, 2025
Received: December 8, 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: 2025.12.18 23:03:25 -05'00'

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

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)*
K253915

Device Name
MOVIVA® Hybrid Ablation Probe

Indications for Use *(Describe)*
MOVIVA is intended for:
• argon plasma coagulation and ablation of the mucosa, with or without lesions.
• needle-free injection and tissue-selective hydrodissection including lifting mucosa by injection into the submucosa.
MOVIVA is indicated for use in endoscopic procedures.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

Applicant

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Contact Person

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Regulatory Affairs Specialist
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Date Prepared

December 16, 2025

Device Information

Trade/Proprietary Name:	MOVIVA
Common Name:	Argon-enhanced endoscopic electrosurgical electrode
Classification Name	Electrosurgical cutting and coagulation device and accessories
Regulation Number:	21 CFR 878.4400
Class:	II
Product Code:	GEI & FQH

Legally Marketed Predicate Devices

Predicate Device
HybridAPC probe (K243120)

Reference Device
ERBEJET® 2 System (K231023)

Device Description

MOVIVA is a flexible, sterile, single use monopolar probe that combines the technologies of hydrosurgery and argon plasma coagulation (APC) in one instrument. Each function can be activated independently without the need to change instruments.
It is used with an Erbe hydrosurgical unit and an Erbe APC unit in combination with an electrosurgical unit (ESU) Erbe VIO Model. The probe is inserted via the working channel of an endoscope with a working channel diameter larger than 2.8 mm. A form-coded marking near the probe tip ensures consistent positioning and orientation during the procedure.
The hydrosurgical function is intended to deliver a pressurized fluid to create a fluid cushion beneath the tissue to be ablated which serves as a mechanical and thermal protection layer for the underlying tissue (muscularis). The electrosurgical (i.e. APC) function is intended for ablation of the lifted tissue. MOVIVA has a shaft length of 1.9 meters, a cable length of 3 meters and an outer diameter (OD) of 2.4 mm.
MOVIVA is connected to the units via respective cables/tubing. The settings or adjustment of application parameters is performed via the units. Activation of the instrument is done using a footswitch.

Indications for Use

MOVIVA is intended for:
- argon plasma coagulation and ablation of the mucosa, with or without lesions.
- needle-free injection and tissue-selective hydrodissection including lifting mucosa by injection into the submucosa.

MOVIVA is indicated for use in endoscopic procedures.

The intended use of the subject device and legally marketed predicate device is the same.
Both the subject and predicate device are intended to supply the same kind of energy, i.e. monopolar high frequency electrical current via ionized, electrically conductive argon plasma for argon plasma coagulation/ablation and a high-pressure water jet. Compared to the predicate device, the wording submucosal injection was replaced by the terms needle-free injection and tissue-selective hydrodissection for clarification and to harmonize the wording with the intended use of its parent device (i.e. reference device ERBEJET 2 system as cleared with K231023).

Comparison of Technological Characteristics

Characteristics	Subject Device MOVIVA	Predicate Device HybridAPC Probe (K243120)	Reference Device Erbejet 2 System (K231023)
Manufacturer	Erbe Elektromedizin GmbH (Germany)	Erbe Elektromedizin GmbH (Germany)	Erbe Elektromedizin GmbH (Germany)
Regulation number	878.4400 & 880.5475	878.4400 & 880.5475	880.5475
Regulatory class	II	II	II
Product code	GEI; FQH	GEI; FQH	FQH
Indications for Use	MOVIVA is intended for: - argon plasma coagulation and ablation of the mucosa, with or without lesions. - needle-free injection and tissue-selective hydrodissection including lifting mucosa by injection into the submucosa. MOVIVA is indicated for use in endoscopic procedures.	The HybridAPC probe is intended for the submucosal injection of sterile normal saline to lift mucosa using direct visualization through an endoscope and for HF ablation of the mucosa, with or without lesions, by Argon Plasma Coagulation (APC). Indications include but are not limited to: • Barrett's esophagus • Ulcers • Arteriovenous Malformations • Angioma • Angiodysplasia • Gastric Antral Vascular Ectasia (GAVE) • Radiation Proctitis • Gastroesophageal reflux disease (GERD) • Post-polypectomy ablation/Post-EMR ablation	The Erbe hydrosurgical unit ERBEJET 2 with instruments and accessories is intended to pressurize a medium to perform needle-free injection and tissue-selective hydrodissection of soft tissue. The Erbe hydrosurgical unit ERBEJET 2 with instruments and accessories is used in endoscopic and surgical procedures. 20150-220: The ERBEJET probe is intended for dissection (tissue-selective hydrodissection) including separation of soft tissue in endoscopic interventions. The ERBEJET probe can be used for needle-free injection including lifting of mucosal lesions by injection into the submucosa.
Prescription or OTC	Prescription	Prescription	Prescription
Compatibility	Erbe APC 3 with VIO 3 /VIO 3n ERBEJET 2	Erbe APC 2 with VIO D or S series Erbe APC 3 with VIO 3 ERBEJET 2	N/A
Materials	Stainless Steel, Tungsten, Plastics	Stainless Steel, Tungsten, Plastics	Plastics, Stainless Steel, Silicone, Synthetic Jewel
Connection (Type)	APC 3 Plug Fluid Plug	APC 2 / 3 Plug Fluid Plug	
Probe Dimensions	Diameter (in mm): 2.4 Length (in m): 1.9	Diameter (in mm): 2.3 Length (in m): 1.9	Diameter (in mm): 1.3 Length (in m): 2.2
Max. electrical load capacity	5000 Vp	5000 Vp	N/A
Energy delivery	Argon plasma (Monopolar high frequency current)	Argon plasma (Monopolar high frequency current)	High pressure water jet

Characteristics	Subject Device MOVIVA	Predicate Device HybridAPC Probe (K243120)	Reference Device Erbejet 2 System (K231023)
	High pressure water jet	High pressure water jet	
Pressure range (Waterjet)	1 - 80bar (+20%)	1 - 80bar (+20%)	1 - 80bar (+20%)
Max. gas flow rate	2.4 l/min	2.4 l/min	N/A
Provided Condition	Sterile, single-use	Sterile, single-use	Sterile, single-use
Sterilization method	Ethylene oxide	Ethylene oxide	Ethylene oxide

The specifications of the subject device are similar compared to the predicate device. Both devices are sterile, single-use devices, apply the same kind of energy, have the same max. electrical load capacity, the same (waterjet) pressure range and maximal gas flow rate.
Compared to the predicate device, the subject device has a protruding electrode, a new design of the switch enclosure, new shaft color and a new plug design. Whereas the design of the switch enclosure, shaft color and plug design have no impact on safety and effectiveness, purpose of the protruding electrode is to optimize the injection success.

To exclude a negative impact on safety and effectiveness and to show substantial equivalence, bench testing was conducted as described below.

Summary of non-clinical bench performance testing

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 in compliance with FDA Guidance “Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery”, issued on March 9, 2020, as applicable.

Side-by-side tissue testing on three different tissue types to compare the injection performance and to determine the fluid cushion height and area.

EMC and Electrical safety of the subject device was tested in compliance with FDA recognized versions of IEC 60601-1; IEC 60601-2-2; IEC 60601-2-18: and IEC 60601-1-2, as applicable.

Biocompatibility testing was performed in compliance with ISO 10993-1 and FDA Guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" to demonstrate biocompatibility of the used materials.

Sterilization validation was performed in compliance with ISO 11135 and documentation was provided according to FDA Guidance “Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile” showing an SAL of 10^{-6}. EO residual testing and limits are in compliance with ISO 10993-7.

Packaging and shelf-life validation was performed in compliance with ISO 11607-1 and accelerated aged (ASTM F 1980) devices.

Conclusion

The subject device has the same intended use, the same fundamental design, substantially equivalent performance characteristics, and the same energy source as the predicate device. The subject device was tested as described above to demonstrate reasonable assurance of safety and effectiveness.

Taken together, 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.