June 20, 2025

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

Re: K243120
Trade/Device Name: HybridAPC 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: May 19, 2025
Received: May 19, 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,

James H. Jang -S

Digitally signed by James H. Jang -S
Date: 2025.06.20 10:21:18 -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243120

Device Name
HybridAPC probe

Indications for Use *(Describe)*
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

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.

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510(k) SUMMARY

Applicant

Erbe Elektromedizin GmbH
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Tel: 0049-7071-755-0
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Contact Person

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Regulatory Affairs Specialist
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Date Prepared

June 20,2025

Device Information

Trade/Proprietary Name:	HybridAPC probe
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

Primary Predicate
ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe (K143306)

Secondary Predicate
ERBE APC Integrated Filter Probes (K060183)

Reference Device
Barrx FLEX RFA Energy Generator (K160360)

Device Description

The HybridAPC probe 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 the hydrosurgical unit Model ERBEJET 2 and an Erbe APC unit in combination with an electrosurgical unit (ESU) VIO Model. The probe is used with endoscopes with a working channel diameter larger than 2.5mm.
The hydrosurgical function is intended to deliver a pressurized fluid to create a fluid cushion beneath the mucosa/mucosal lesion to be ablated which serves as a mechanical and thermal protection layer for the underlying tissue and to reduce the risk of perforations. The electrosurgical (i.e. APC) function is intended for ablation of the lifted mucosa/mucosal lesion. The Hybrid APC probe has a length of 1.9 meters and an outer diameter (OD) of 2.3mm.
The HybridAPC probe is connected to the units via respective cables/tubings. The settings or adjustment of application parameters is performed via the units. Activation of the instrument is done using a footswitch.

Indications for Use

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 intended use of the subject device and legally marketed predicate device(s) is the same. Both the primary and secondary 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 of tissue. The reference device supplies (bipolar) high frequency electrical current for coagulation of soft tissue. In addition, the subject and primary predicate device supply sterile normal saline into the submucosa to lift the mucosa/mucosal lesion to be coagulated/ablated as an additional safety feature.

Whereas the primary predicate device is only indicated for lifting and ablation of mucosal lesions, the subject device is indicated for both mucosal lesions and mucosa analogous to the secondary predicate device which has a comparable APC function. The reference device Barrx in combination with compatible instruments which has an equivalent mode of action (i.e.

application of HF electrical current) is also not limited to lesions.
In addition, various indications were added. To substantiate the modified indications for use statement, real-world evidence in form of clinical data (peer-reviewed literature) was provided in accordance with FDA Guidance "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices", showing that the added indications are well-established and routinely used in clinical practice with the subject device. A safety analysis which is derived from the provided literature concludes that the label expansion doesn´t create any increase in device-specific risks and that the reported complications are consistent with expected outcomes from similar procedures. HybridAPC or APC alone is safe and effective for the added indications and the specific use does not introduce new risks which are not normally associated with the general use.

The Barrx RFA Energy Generator in combination with compatible probes is used as a reference device as an example of a RF electrosurgical ablation device which is also cleared for most indications which are added for the subject device.

Comparison of Technological Characteristics

Characteristics	**Predicate Devices**		**Reference Device**	**Subject Device**
	Primary ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe (K143306)	Secondary ERBE APC Integrated Filter Probes (K060183)	Barrx FLEX RFA Energy Generator (K160360)	HybridAPC Probe
Manufacturer	Erbe Elektromedizin GmbH (Germany)	Erbe Elektromedizin GmbH (Germany)	Covidien LLC	Erbe Elektromedizin GmbH (Germany)
Regulation number	878.4400	878.4400	878.4400	878.4400
Regulatory class	II	II	II	II
Product code	GEI; FQH	GEI	GEI	GEI; FQH
Indications for Use	The HybridAPC probe is indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions using direct visualization through an endoscope and for HF ablation of the mucosal lesion by Argon Plasma Coagulation (APC).	The APC Integrated Filter Probes are intended for use in Argon Plasma Coagulation (APC). The devices are used to treat many conditions in endoscopy for various surgical procedures.	The Barrx FLEX RFA Energy Generator is indicated for use in the coagulation of soft tissue. The Barrx FLEX RFA Energy Generator is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to the esophagus.	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:

Characteristics	Predicate Devices		Reference Device	Subject Device
	Primary ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe (K143306)	Secondary ERBE APC Integrated Filter Probes (K060183)	Barrx FLEX RFA Energy Generator (K160360)	HybridAPC Probe
			Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions and Angiodysplasia. The Barrx FLEX RFA Energy Generator is used with various RF catheters which include: x Barrx™ 360 RFA Balloon Catheter and Barrx™ Soft Sizing Balloon (K093855) x Barrx™ 90 RFA Focal Catheter (K093008) x Barrx™ 60 RFA Focal Catheter (K112454) x Barrx™ ULTRA Long RFA Focal Catheter (K120431) x Barrx™ Channel RFA Endoscopic Catheter (K130623) x Barrx™ RFA Self Sizing Balloon Catheter (K142364) x Barrx™ Anorectal RFA Wand (150251)	• 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
Prescription or OTC	Prescription	Prescription	Prescription	Prescription

Characteristics	Predicate Devices		Reference Device	Subject Device
	Primary ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe (K143306)	Secondary ERBE APC Integrated Filter Probes (K060183)	Barrx FLEX RFA Energy Generator (K160360)	HybridAPC Probe
Compatibility	Erbe APC 2 with VIO D or S series Erbe APC 3 with VIO 3 ERBEJET 2	Erbe APC 300 with ICC series Erbe APC 2 with VIO series Erbe APC 3 with VIO 3	Various RFA instruments	Erbe APC 2 with VIO D or S series Erbe APC 3 with VIO 3 ERBEJET 2
Materials	Stainless Steel, Tungsten, Plastics	Stainless steel, plastics, tungsten, ceramics	Unknown	Stainless Steel, Tungsten, Plastics
Probe Dimensions	Diameter (in mm): 2.3 Length (in m): 1.9	Diameter (in mm): 1.5; 2.3; 3.2 Length (in m): 1.5; 2.2; 3.0	Shaft diameter (in mm): 2.5, 4, 7 Catheter shaft length (in m): 0.85, 1.35, 1.60, 1.62 Electrode length (in cm): 1.5, 1.57, 2, 4	Diameter (in mm): 2.3 Length (in m): 1.9
Nozzle/ Jet diameter	120 µm	N/A	N/A	120 µm
Max. electrical load capacity	5000 Vp	5000 Vp	Unknown	5000 Vp
Energy delivery	Argon plasma (Monopolar high frequency current) High pressure water jet	Argon plasma (Monopolar high frequency current)	Bipolar high frequency current	Argon plasma (Monopolar high frequency current) High pressure water jet
Pressure range (Waterjet)	1 - 80bar (+/- 20%) / 14.5 - 1160.3psi (+/- 20%)	N/A	N/A	1 - 80bar (+/-20%) / 14.5 - 1160.3psi (+/- 20%)
Max. gas flow rate	2.4 l/min	2.4 l/min	N/A	2.4 l/min
Provided Condition	Sterile, single-use	Sterile, single-use	Sterile, single-use	Sterile, single-use
Sterilization method	Ethylene oxide	Ethylene oxide	Unknown	Ethylene oxide

Compared to the primary predicate device, the subject device is the same. Since the initial clearance (K143306), there were no changes to the design, materials, or performance characteristics.
The secondary predicate ERBE APC Integrated Filter Probes (K060183) has the same basic design compared to the subject device. Both devices are flexible, single-use, sterile probes which provide monopolar HF current in form of an argon plasma. There are several variants of the secondary predicate device, one of which has the same OD as the subject device and a similar length. The secondary predicate and subject device have the same max. gas flow rate, electrical load capacity, can be used with the same modes/parent devices and have similar materials. Basically, the subject device is an iteration of the secondary predicate device that adds the capability of providing a waterjet as an additional safety feature, while maintaining the same APC function and performance. Due to these great similarities and the fact that the secondary predicate is cleared with a tool-type intended use (argon-plasma coagulation (of tissue)), it is justifiable to slightly modify the indications for use of the subject device from lifting and ablation of mucosal lesions to lifting and ablation of mucosa/mucosal lesions.
In addition, the systematic literature review and meta-analysis evaluated the safety and performance of the subject device for both non-lesioned and lesioned mucosa. Data from various studies, involving more than 1,900 patients for safety and more than 1,200 patients/lesions for performance outcomes, consistently indicate that use of the subject device on non-lesioned mucosa achieves strong efficacy with no additional risk compared to its established use on lesioned tissue.
The compatible probes which can be used with the reference device Barrx have a similar diameter and shaft length compared to the subject device. Whereas the subject device applies monopolar HF current in form of an argon plasma contact free, the reference device has an electrode which applies bipolar HF current in direct tissue contact. Although there are some technological differences, both the subject and the reference device supply high frequency (HF) electrical current to thermally effect or destroy tissue. Since the reference device in combination with compatible probes is cleared for various indications which are also proposed for the subject device and the mode of action is similar, the Barrx is used as a reference device.

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.

Tissue testing to validate the lifting function and the thermal effect.

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) + real-time aged 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(s).

The added indications for use are justified based on the real-world evidence which was provided according to FDA Guidance “Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices”. Real-world evidence in form of peer-reviewed literature shows that the device is safe and effective for the proposed indications and doesn´t create any new risks compared to the general use of the device. The reference device was chosen to further substantiate the added indications since both the subject and the reference device have a similar mode of action and supply high frequency (HF) electrical current to thermally effect or destroy tissue.

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(s) for the requested indications for use.