November 29, 2023

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

Re: K232033
Trade/Device Name: HYBRIDknife® flex
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, FQH
Dated: October 30, 2023
Received: October 31, 2023

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.

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.11.29 13:06:33 -05'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K232033

Device Name
HYBRIDknife® flex

Indications for Use *(Describe)*
The HYBRIDknife flex is intended for:
• monopolar cutting and coagulation.
• needle-free injection and tissue-selective hydrodissection including lifting mucosal lesions by injection into the submucosa (soft tissue).
The HYBRIDknife flex is used in endoscopic interventions.

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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510(k) SUMMARY

Applicant

Erbe Elektromedizin GmbH
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Contact Person

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

Date Prepared

November 29, 2023

Device Information

Trade/Proprietary Name:	HYBRIDknife® flex
Common Name:	Monopolar probe with hydro function
Classification Name	Electrosurgical cutting and coagulation device and accessories & Jet Lavage
Regulation Number:	21 CFR 878.4400 & 21 CFR Part 880.5475
Class:	II
Product Code:	GEI & FQH

Legally Marketed Predicate Devices

Primary: ERBE Hybrid Knife - K083608
Secondary: ERBEJET® 2 System K231023

Device Description

The HYBRIDknife flex is a flexible monopolar probe that combines the technologies of hydrosurgery and electrosurgery in one instrument.
Each function can be activated without the need to change instruments. The HYBRIDknife flex is a sterile, single use device which is used with endoscopes with a minimal working channel diameter of 2.8mm. The hydrosurgical function is intended to deliver a pressurized fluid for tissue-selective hydrodissection and needle-free injection whereas the electrosurgical function is intended for cutting and coagulation of tissue. By means of needle-free injection a fluid cushion is formed in the submucosa, which provides a mechanical and thermal protection layer during cutting and coagulation of the target tissue. The elevation thus reduces the risk of perforation. All HYBRIDknife flex probes have a length of 2.3 meters and an outer diameter (OD) of 2.6mm. The only difference between the variants is the electrode type and length. The HYBRIDknife flex is available with a “T-type” electrode and an “I-type” electrode whereas both electrode types are available as a long (i.e. 2mm length) and short (i.e. 1.5mm) version. The protrusion of the T-type electrode gives the user the possibility to hook and move tissue.
The instruments are designed for operation with the hydrosurgical unit ERBEJET 2 (K072404; K143306 & K231023) in combination with an Erbe Electrosurgical unit of the “VIO” series (e.g. VIO 3 K190823). HYBRIDknife flex 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 by using a footswitch.

Indications for Use

The HYBRIDknife flex is intended for:
- monopolar cutting and coagulation.
- needle-free injection and tissue-selective hydrodissection including lifting mucosal lesions by injection into the submucosa (soft tissue).

The HYBRIDknife flex is used in endoscopic interventions.

Comparison to predicate devices

Characteristics	Predicate Devices		Subject Device
	Primary Predicate Device ERBE Hybrid Knife (K083608)	**Secondary Predicate Device Erbejet 2 System (K231023)**	**HYBRIDknife flex**
Manufacturer	Erbe Elektromedizin GmbH (Germany)	Erbe Elektromedizin GmbH (Germany)	Erbe Elektromedizin GmbH (Germany)
Regulation number	878.4400 & 880.5475	880.5475	878.4400 & 880.5475
Regulatory class	II	II	II
Product code	GEI; FQH	FQH	GEI; FQH
Indications for use	The ERBE Hybrid Knife is intended to be used in combination with the Water Jet System/ERBEJET 2 and an ERBE ESU VIO Model to cut and dissect soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME) via the Water Jet System as well as to provide monopolar cutting and coagulation of the target tissue by the ESU in open and as well as endoscopic surgery.	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.	The HYBRIDknife flex is intended for: • monopolar cutting and coagulation. • needle-free injection and tissue-selective hydrodissection including lifting mucosal lesions by injection into the submucosa (soft tissue). The HYBRIDknife flex is used in endoscopic interventions.
Prescription or OTC	Prescription	Prescription	Prescription
Materials	Plastics, Teflon, and Stainless Steel	Plastics, Stainless Steel, Silicone, Synthetic Jewel	Stainless Steel, Tungsten, Ceramics, Plastics
Probe Dimensions	Outer Diameter (O.D.) 2mm x Length 2.2m	O.D. 1.3mm x Length 2.2m	O.D. 2,6mm x Length 2.3m
Nozzle Dimensions	120µm	120µm	120µm

Characteristics	Predicate Devices		Subject Device
	Primary Predicate Device ERBE Hybrid Knife (K083608)	**Secondary Predicate Device Erbejet 2 System (K231023)**	**HYBRIDknife flex**
Electrode type and dimensions	I-type and T-type electrode T-Type Length: 5.5mm Diameter: 0.7mm T-plate diameter: 1.6mm T-plate thickness: 0.3mm I-Type Length: 5.0mm Diameter: 0.7mm	N/A	I-type and T-type electrode T-Type short Length: 1.5mm Diameter: 0.5mm T-plate diameter: 1.2mm T-plate thickness: 0.3mm T-Type long Length: 2.0mm Diameter: 0.5mm T-plate diameter: 1.2mm T-plate thickness: 0.3mm I-Type short Length: 1.5mm Diameter: 0.5mm I-Type long Length: 2.0mm Diameter: 0.5mm
Physical characteristics	Probe with Retractable electrode (adjustable)	N/A	Probe with Retractable Electrode (Only two states are possible: electrode retracted and extended). Modified handle design (Electrode slider with latching function and thumb loop)
Energy delivery	High Frequency (HF) Current with a maximum Electrical Capacity of 2500 Vp. Pressurized Sterile Normal Saline from Effect 1 to 80 which corresponds from 14.5 to 1,160.3 psi	N/A Pressurized Sterile Normal Saline with or without dye additives from Effect 1 to 80 which corresponds from 14.5 to 1,160.3 psi	High Frequency (HF) Current with a maximum Electrical Capacity 4500 Vp. Pressurized Sterile Normal Saline with or without dye additives from Effect 1 to 60 which corresponds to a max. impact force between 0.04 – 0.063 N (14.5 to 870.2 psi).
Condition Provided/ Use Condition	Sterile, single-use	Sterile, single-use	Sterile, single-use
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide

Comparison of Technological Characteristics with the Predicate Device

The subject device has a higher dielectric strength compared to the primary predicate device. In addition, the subject device is slightly thicker, longer, more flexible and the electrode is shorter and thinner compared to the primary predicate device to allow finer cuts. While the electrode is adjustable with the primary predicate device the subject device only allows two electrode states (retracted and extended). The subject device has different materials compared to the primary predicate device.

Regarding the waterjet function, the subject device has the same operating principle and nozzle diameter compared to both predicate devices (i.e. Erbe Hybrid Knife and ERBEJET 2 with ERBEJET probe). As shown by respective tissue testing, the subject device HYBRIDknife flex creates equivalent fluid cushions as the primary predicate device.

The different materials have no impact on safety as shown by biocompatibility testing in compliance with ISO 10993.

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.

Tissue testing was performed in compliance with FDA Guidance “Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery”, issued on March 9, 2020, to validate cutting and coagulation performance and the waterjet function compared to the predicate device.

EMC and Electrical safety of the subject device was tested in compliance with IEC 60601-1 Edition 3.2; IEC 60601-2-2 Edition 6.0; IEC 60601-2-18: Edition 3.0 and IEC 60601-1-2 Edition 4.0

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

with the new materials that were used.

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 devices (ASTM F 1980).

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 devices. The subject device was tested as described above and the minor differences in technological characteristics were assessed with regards to 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 devices.