August 26, 2024

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

Re: K242044
Trade/Device Name: FiAPC plus probes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 12, 2024
Received: July 12, 2024

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.08.26 10:37:08 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
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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)*
K242044

Device Name

FiAPC plus probes

Indications for Use *(Describe)*

The flexible FiAPC probes are intended for argon plasma coagulation and ablation of tissue.

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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Germany
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Contact Person

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

Date Prepared July 12, 2024

Device Information

Trade/Proprietary Name:	FiAPC® plus probes
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

Legally Marketed Predicate Devices ERBE APC INTEGRATED FILTER PROBES; ERBE APC INTEGRATED FILTER PROBE ADAPTER - K060183

Device Description

The FiAPC® plus probes are sterile, single-use flexible probes intended for argon plasma coagulation (APC) and ablation of tissue. The probes have a plug on the proximal end that enables the connection to the compatible electrosurgical unit (ESU) and APC unit. The plug is ergonomically designed and contains a filter that isolates the device side from the patient side. The plug also contains an instrument recognition which ensures that the instrument can only be operated with the compatible parent devices. The connector is followed by a long tube so that the probe can be inserted into the working channel of an endoscope. At the distal end there is an opening through which the argon plasma is released. The flexible FiAPC® plus probes are available in different variants. All variants have the same outer diameter but differ in their length and distal opening, i.e. axial opening (straight fire) or lateral opening (side fire).

Indications for Use

The flexible FiAPC probes are intended for argon plasma coagulation and ablation of tissue.

The intended use of the subject device and legally marketed predicate device is the same. Compared to the predicate device, the indications for use statement of the subject device additionally includes the term ablation of tissue for clarification in accordance with the parent device APC 3 (K191234) which was cleared for “argon plasma coagulation and ablation of tissue” … ”when used in conjunction with a compatible Erbe VIO Electrosurgical Generator (ESU) and applicators or probes”

Comparison of Technological Characteristics

Characteristics	Subject Device	Predicate Device	Comments
	FiAPC® plus probes	Argon Plasma Coagulation (APC) Integrated Filter Probes and Adapter K060183	
Manufacturer	Erbe Elektromedizin GmbH (Germany)	Erbe Elektromedizin GmbH (Germany)	Same
Regulation number	878.4400	878.4400	Same
Regulatory class	II	II	Same
Product code	GEI	GEI	Same
Indications for use	The flexible FiAPC probes are intended for argon plasma coagulation and ablation of tissue.	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.	Same Intended Use
Prescription or OTC	Prescription	Prescription	Same
Compatibility	Erbe APC 2 with VIO D or S series	Erbe APC 300 with ICC series Erbe APC 2 with VIO series	Similar

<table>
<tr><td></td><td>Erbe APC 3 with VIO 3</td><td>Erbe APC 3 with VIO 3</td><td></td></tr>
<tr><td>Materials</td><td>Stainless steel, plastics, ceramics, silver</td><td>Stainless steel, plastics, tungsten, ceramics</td><td>Similar</td></tr>
<tr><td>Beam Type</td><td>Axial and lateral (sidefire)</td><td>Axial, lateral (sidefire) and circumferential</td><td>Similar</td></tr>
<tr><td>Probe Dimensions</td><td><table><tr><th>Beam form</th><th>Diameter [mm]</th><th>Length [m]</th></tr><tr><td>Axial</td><td>2.3</td><td>2.2</td></tr><tr><td>Axial</td><td>2.3</td><td>3.0</td></tr><tr><td>Sidefire</td><td>2.3</td><td>2.2</td></tr></table></td><td><table><tr><th>Beam form</th><th>Diameter [mm]</th><th>Length [m]</th></tr><tr><td>Axial</td><td>1.5</td><td>1.5</td></tr><tr><td>Axial</td><td>1.5</td><td>3.0</td></tr><tr><td>Axial</td><td>2.3</td><td>2.2</td></tr><tr><td>Axial</td><td>2.3</td><td>3.0</td></tr><tr><td>Axial</td><td>3.2</td><td>2.2</td></tr><tr><td>Sidefire</td><td>2.3</td><td>2.2</td></tr><tr><td>Circumf.</td><td>2.3</td><td>2.2</td></tr></table></td><td>Similar; optimized design of the distal end (rounded tip)</td></tr>
<tr><td>Plug</td><td>Filter integrated plug with instrument recognition</td><td>Filter integrated plug with instrument recognition</td><td>Similar; optimized plug design</td></tr>
<tr><td>Max. electrical load capacity</td><td>5000 Vp</td><td>5000 Vp</td><td>Same</td></tr>
<tr><td>Max. gas flow rate</td><td>2.4 l/min</td><td>2.4 l/min</td><td>Same</td></tr>
<tr><td>Energy delivery</td><td>Argon plasma (Monopolar high frequency current)</td><td>Argon plasma (Monopolar high frequency current)</td><td>Same</td></tr>
<tr><td>Condition Provided/ Use Condition</td><td>Sterile, single-use</td><td>Sterile, single-use</td><td>Same</td></tr>
<tr><td>Sterilization Method</td><td>Ethylene Oxide</td><td>Ethylene Oxide</td><td>Same</td></tr>
</table>

The specifications of the subject device are largely identical compared to the predicate device. Both devices are sterile, single-use devices which apply the same kind of energy, offer the same beam types, have the same probe dimensions, a filter integrated plug and the same max. electrical load capacity.
Minor differences are related to the plug design, the design of the distal tip and the used materials.

To exclude a negative impact on safety and effectiveness and to show substantial equivalence, side-by-side tissue testing was conducted in compliance with FDA Guidance “Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery”, issued on March 9, 2020. Compared to the predicate device, the subject device showed comparable tissue effects and comparable ignition distances.
As shown by bench testing, all design and performance requirements were successfully verified/validated, and all acceptance criteria are met. Biocompatibility testing in compliance with FDA recognized consensus standard ISO 10993-1 shows that the new materials are biocompatible. The provided testing demonstrates that the subject device is as safe and effective as the legally marketed predicate devices and does not raise new or different questions of safety and effectiveness.

Summary of non-clinical bench 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 device.

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 the thermal effect on tissue compared to the predicate device.

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 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 device. 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 device.