April 22, 2026

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

Re: K253230
Trade/Device Name: ERBECRYO 2 Cryosurgical Unit and Accessories: ERBECRYO 2 cryosurgical unit; Erbe Flexible Cryoprobe
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: September 29, 2025
Received: March 19, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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: 2026.04.22 21:59:05 -04'00'

Colin K. Chen, 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

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.	K253230

Please provide the device trade name(s).

ERBECRYO 2 Cryosurgical Unit and Accessories: ERBECRYO 2 cryosurgical unit; Erbe Flexible Cryoprobe

Please provide your Indications for Use below.

Indications for Use statement for the ERBECRYO 2 cryosurgical unit:

The ERBECRYO 2 cryosurgical unit and accessories are intended for cryoadhesion and devitalization (destruction) of tissue by the application of extreme cold.

Indications for Use statement for the Erbe Flexible Cryoprobes:

The Erbe Flexible Cryoprobes are intended for palliative devitalization (destruction) of tissue during interventional procedures by the application of extreme cold and cryoadhesion for applications such as the removal of foreign bodies, mucus plugs, blood clots, necrotic tissue, tissue tumors (palliative recanalization) and tissue biopsies.

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 Waldhoernlestrasse 17 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 21, 2026
Device Information	
Trade/Proprietary Name:	ERBECRYO 2 Cryosurgical Unit and Accessories; Erbe Flexible Cryoprobes
Common Name:	Cryosurgical Unit; Endoscopic cryosurgical probe
Classification Name	Cryosurgical Unit & Accessories
Regulation Number:	21 CFR 878.4350
Class:	II
Product Code:	GEH
Legally Marketed Predicate Devices	ERBECRYO® 2 Cryosurgical Unit and Accessories - K190651

Device Description

The ERBECRYO 2 unit consists of a steel casing with an aluminum casing button. The plastic face frame comprises the power switch, a plastic receptacle, and a LED display with a membrane keypad. Inside the housing the hardware components are installed. These are the electrical mains supply, the main board (central control unit), the user interface, the gas flow and control module, the flow sensor module and connection sockets for the Flexible Cryoprobes, the footswitch and ECB (Erbe communication bus).
The Unit is connected to an electrical power source, a Carbon Dioxide (CO_2) source, the footswitch, and an instrument. Upon activation via the pedal of the footswitch, the Unit delivers the regulated CO_2 flow to the end of the connected instrument.

The Flexible Cryoprobes are sterile, single-use flexible probes that are connected to the parent device ERBECRYO 2 for palliative devitalization (destruction) of tissue during interventional procedures by the application of extreme cold and cryoadhesion for applications such as the removal of foreign bodies, mucus plugs, blood clots, necrotic tissue, tissue tumors (palliative recanalization) and tissue biopsies in combination with a cryosurgical unit.

Device Modification

Compared to the initial clearance (K190651), an elongated variant of the Flexible Cryoprobes is added. The new variant has the same materials, operating principle, and fundamental design as the already cleared variants. The only difference is a longer distal end.

Indications for Use

The Erbe Flexible Cryoprobes are intended for palliative devitalization (destruction) of tissue during interventional procedures by the application of extreme cold and cryoadhesion for applications such as the removal of foreign bodies, mucus plugs, blood clots, necrotic tissue, tissue tumors (palliative recanalization) and tissue biopsies.

Comparison of Technological Characteristics

ERBECRYO 2

Besides labeling changes due to updated risk management (not related to the elongated cryoprobe), there were no changes to the design, operating principle, software or performance specifications of the parent device ERBECRYO 2 compared to the last clearance K190651.

Flexible Cryoprobes

<table>
<tr><th rowspan="2">Characteristics</th><th>Subject Device</th><th>Predicate Device</th><th rowspan="2">Comparison</th></tr>
<tr><td>Flexible Cryoprobe</td><td>Flexible Cryoprobes
K190651</td></tr>
<tr><td>Manufacturer</td><td>Erbe Elektromedizin GmbH (Germany)</td><td>Erbe Elektromedizin GmbH (Germany)</td><td>Same</td></tr>
<tr><td>Regulation number</td><td>878.4350</td><td>878.4350</td><td>Same</td></tr>
<tr><td>Regulatory class</td><td>II</td><td>II</td><td>Same</td></tr>
<tr><td>Product code</td><td>GEH</td><td>GEH</td><td>Same</td></tr>
<tr><td>Indications for use</td><td>The Erbe Flexible Cryoprobes are intended for palliative devitalization (destruction) of tissue during interventional procedures by the application of extreme cold and cryoadhesion for applications such as the removal of foreign bodies, mucus plugs, blood clots, necrotic tissue, tissue tumors (palliative recanalization) and tissue biopsies.</td><td>The Erbe Flexible Cryoprobes are intended for palliative devitalization (destruction) of tissue during interventional procedures by the application of extreme cold and cryoadhesion for applications such as the removal of foreign bodies, mucus plugs, blood clots, necrotic tissue, tissue tumors (palliative recanalization) and tissue biopsies.</td><td>Same</td></tr>
<tr><td>Prescription or OTC</td><td>Prescription</td><td>Prescription</td><td>Same</td></tr>
<tr><td>Compatibility</td><td>ERBECRYO 2</td><td>ERBECRYO 2</td><td>Same</td></tr>
<tr><td>Materials</td><td>Stainless steel, silicone, plastics, printing color, adhesive</td><td>Stainless steel, silicone, plastics, printing color, adhesive</td><td>Same</td></tr>
<tr><td>Probe Dimensions</td><td><table><tr><th>OD [mm]</th><th>Length [mm]</th><th>Over-sheath</th></tr><tr><td>1.7</td><td>2550</td><td>N/A</td></tr></table></td><td><table><tr><th>OD [mm]</th><th>Length [mm]</th><th>Over-sheath</th></tr><tr><td>1.1</td><td>1150</td><td>OD 2.6mm L 817mm</td></tr><tr><td>1.1</td><td>1150</td><td>OD 2.6mm L 757mm</td></tr><tr><td>1.7</td><td>1150</td><td>N/A</td></tr><tr><td>2.4</td><td>1150</td><td>N/A</td></tr></table></td><td>Increased length based on cleared probe with OD of 1.7mm.</td></tr>
<tr><td>Input pressure</td><td>769 psi to 943 psi (53 bar to 65 bar)</td><td>769 psi to 943 psi (53 bar to 65 bar)</td><td>Same</td></tr>
<tr><td>Energy delivery</td><td>Cooling by means of CO_2 (Joule-Thomson Effect)</td><td>Cooling by means of CO_2 (Joule-Thomson Effect)</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>Shelf-life</td><td>3 years</td><td>3 years</td><td></td></tr>
<tr><td>Sterilization Method</td><td>Ethylene Oxide</td><td>Ethylene Oxide</td><td>Same</td></tr>
</table>

The modified Flexible Cryoprobe is based on the cleared variant with an OD of 1.7mm. Compared to the cleared variant, the only difference is an increased distal length (Modified device: 2550mm compared to cleared device: 1150mm). All other technological characteristics such as materials, operating principle, energy type and fundamental design are identical. The modified and cleared probe variants have the same intended use. Non-clinical bench performance testing and safety considerations as described below demonstrate that the modified and cleared probe variants are substantially equivalent.

Safety Considerations

Due to the length disparity between the subject and the predicate device, a benefit-risk discussion was provided in compliance with FDA Guidance "Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics", demonstrating an improved benefit-risk profile (partially improved benefits while sharing the same risks) compared to the predicate device for the anticipated use in the GI tract.

To substantiate the anticipated application in the GI tract, real-world evidence in form of peer reviewed literature including a randomized controlled trial was provided to demonstrate safety and effectiveness of the elongated probe.

Summary of non-clinical bench performance testing

Functional testing and design controls to verify both safety and performance of the subject device based on the risk analysis according to ISO 14971 was performed in compliance with ISO 13485, clause 7.3 to ensure that the subject device performs as intended and meets design specifications.

Side-by-side tissue testing was conducted to demonstrate equivalent freezing performance of the subject device compared to the predicate device by measuring the mean biopsy size in a standardized ex vivo setup including common activation times for cryoprobes and the simulation of the application conditions in the human body. Testing was performed on different tissue types to cover a range of tissue densities.

Sterilization validation was performed in compliance with ISO 11135 showing an SAL of 10-6. EO residual testing and limits are in compliance with ISO 10993-7.

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.

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

Electromagnetic compatibility (EMC) was tested in compliance with IEC 60601-1-2 and FDA

Guidance “Electromagnetic Compatibility (EMC) of Medical Devices”.

Electrical safety was tested in compliance with IEC 60601-1.

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” and the device complies with FDA Guidance “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions”.

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 of the elongated cryoprobe. 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.