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

June 9, 2026

Re: K261806
Trade/Device Name: ERBECRYO 2 Cryosurgical Unit and Accessories
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: June 1, 2026
Received: June 1, 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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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: 2026.06.09 08:54:46 -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

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)*
K261806

Device Name
ERBECRYO 2 Cryosurgical Unit and Accessories

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

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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@erbegroup.com

Date Prepared

June 01, 2026

Device Information

Trade/Proprietary Name:	ERBECRYO 2 Cryosurgical Unit and Accessories
Common Name:	Cryosurgical Unit
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 & K253230

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 compatible instruments, 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.

Indications for Use

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

Comparison of Technological Characteristics

ERBECRYO 2

Characteristics	Subject Device ERBECRYO 2 Cryosurgical Unit and Accessories	Predicate Device ERBECRYO 2 Cryosurgical Unit and Accessories	Discussion
510(k) Number	N/A	K190651 & K253230	Different
Model Name	ERBECRYO® 2 Cryosurgical Unit and Accessories	ERBECRYO® 2 Cryosurgical Unit and Accessories	Same
Manufacturer	Erbe Elektromedizin GmbH	Erbe Elektromedizin GmbH	Same
Common Name	Cryosurgical Unit and Accessories	Cryosurgical Unit and Accessories	Same
Classification Regulation	21 CFR 878.4350	21 CFR 878.4350	Same
Product Code	GEH	GEH	Same
Device Class	II	II	Same
Indications for Use	The ERBECRYO 2 cryosurgical unit and accessories are intended for cryoadhesion and devitalization (destruction) of tissue by the application of extreme cold.	The ERBECRYO® 2 cryosurgical unit and accessories are intended for cryoadhesion and devitalization (destruction) of tissue by the application of extreme cold.	Same
Intended Use	Supply of CO_2 to a connected instrument for	Supply of CO_2 to a connected instrument for	Same

Characteristics	Subject Device ERBECRYO 2 Cryosurgical Unit and Accessories	Predicate Device ERBECRYO 2 Cryosurgical Unit and Accessories	Discussion
	cooling via the Joule-Thompson effect.	cooling via the Joule-Thompson effect.	
Prescription or OTC	Prescription	Prescription	Same
Materials	Metal sheet, aluminum, copper pipes, plastics and wiring, electronic components	Metal sheet, aluminum, copper pipes, plastics and wiring, electronic components	Same
Dimensions of Unit	16.1”x5.1”x14.6” 410x130x370mm)	16.1”x5.1”x14.6” 410x130x370mm)	Same
Weight of Unit	14.8lbs (6.7kg)	14.8lbs (6.7kg)	Same
Technical Data of Unit	Rated supply voltage: 100 - 240V (±10%)	Rated supply voltage: 100 - 240V (±10%)	Same
	Rated supply frequency: 50 - 60Hz	Rated supply frequency: 50 - 60Hz	Same
	Line current: 0.4 - 0.8A	Line current: 0.4 - 0.8A	Same
Software Version	1.0.4	1.0.3	Different
Performance Data of Unit	No. of effect levels: 1 - 5 (depending on instrument)	No. of effect levels: 1 - 5 (depending on instrument)	Same
	Activation: via footswitch	Activation: via footswitch	Same
	Cooling gas used: CO_2	Cooling gas used: CO_2	Same
	Input Pressure: 653 - 943psi (45 - 65bar)	Input Pressure: 653 - 943psi (45 - 65bar)	Same
Provided Condition	Non-sterile, reusable	Non-sterile, reusable	Same

The intended use of the subject and predicate device is the same.

Compared to previously cleared device, the software of the subject device was updated to detect defects in connected Cryoprobes to stop operation in cases of an unusual pressure rise.
Besides the updated software, the subject device has the same design, operating principle, and (performance) specifications compared to the cleared device.

Summary of non-clinical bench performance testing

To show safety and effectiveness of the subject device with updated software version, software verification in compliance with FDA recognized consensus standard IEC 62304 was performed to demonstrate that the updated software works as intended.

Functional testing to validate the software update was conducted based on the risk analysis according to ISO 14971 in compliance with ISO 13485, clause 7.3 to ensure that the subject device performs as intended and meets design specifications.

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 software update was tested as described above and assessed with regards to safety and effectiveness. Taken together, the software update of 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.