January 7, 2020

Erbe Elektromedizin GmbH
Henry Kutz
Specialist Regulatory Affairs
Waldhoernlestrasse 17
Tuebingen, Germany 72072

Re: K190651
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: December 4, 2019
Received: December 6, 2019

Dear Henry Kutz:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 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
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190651

Device Name
ERBECRYO 2 Cryosurgical Unit and Accessories

Indications for Use *(Describe)*

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."

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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Erbe Elektromedizin GmbH
Traditional 510(k) for ERBECRYO® 2 Cryosurgical Unit and Accessories

K190651 510(k) SUMMARY
[AS REQUIRED BY 21 CFR 807.92(C)]

Submitted By:	Erbe Elektromedizin GmbH Waldhoernlestrasse 17 72072 Tuebingen Germany Tel: 0049-7071-755-0 Fax: 0049-7071-755-179
Contact Person:	Mr. Henry Kutz Specialist Regulatory Affairs
Date Prepared:	January 6th, 2020
Trade/Proprietary Name:	ERBECRYO® 2 Cryosurgical Unit and Accessories
Common Name:	Cryosurgical Unit and Accessories
Classification Name and Code:	Cryosurgical Unit & Accessories (21 CFR 878.4350)
Regulatory Class:	II
Product Code:	GEH
Legally Marketed Predicate Device:	ERBE ERBECRYO 2 Cryosurgical Unit and Accessories - K151041

Device Description:
The ERBECRYO® 2 Unit and Accessories are manufactured with various metals, plastics, silicone, adhesive, etc. The system consists of connecting hoses, an adapter, a switching valve (optional for using two gas cylinders), the Unit, electrical cables, the footswitch, and the flexible cryoprobes. The ERBECRYO® 2 unit is a standalone unit that can be placed on a table top or secured on a cart. The Cryosurgical Unit has a monochromatic display that provides operational information. The display is surrounded by buttons allowing for user interface (e.g., set the effect, select a program, etc.). Default settings are also displayed per the cryoprobe that is attached. The Cryorugical Unit is connected to an electrical power source, a carbon dioxide (CO_2) source, the footswitch and a flexible cryoprobe. The Cryosurgical Unit displays errors and/or emits audio alarms to alert users of malfunctions or user errors. Typically, a cryoprobe is placed down the working channel of an endoscope (e.g., bronchoscope, etc.) that can accommodate the dimensional attributes (i.e., outer diameter and length) of the probe. Upon activation via the pedal of the footswitch, the Unit delivers the regulated flow of the CO_2 to the tip of the flexible cryoprobe. Through the Joule-Thomson Effect and in the presence of moisture, an ice is formed and surrounding tissue is cooled. The extreme cold is used for cryoadhesion and/or devitalization (i.e., the destruction) of target tissue (Note: The smaller 1.1mm single use cryoprobes have an oversheath so that tissue frozen to the tip can be removed through the endoscope without having to remove the scope from the patient.). The Unit and all of the Accessories, except for the single use flexible cryoprobes, are supplied non-sterile and are reusable. The single use cryoprobes are provided sterile and are single patient use.

Intended Use / Indications for Use

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."

Similarities and Differences of the Modified Device to the Current Device (Predicate Comparison/Substantial Equivalence):

Characteristics	**K151041 ERBECRYO 2 Cryosurgical Unit and Accessories**	**K190651 ERBECRYO® 2 Cryosurgical Unit and Accessories**
Manufacturer	Erbe Elektromedizin GmbH (Germany)	Same
Submitter	Erbe USA Inc. (USA)	Erbe Elektromedizin GmbH (Germany)
Trade/ Proprietary Name	ERBE ERBECRYO 2 Cryosurgical Unit and Accessories	ERBECRYO® 2 Cryosurgical Unit and Accessories

Characteristics	K151041 ERBECRYO 2 Cryosurgical Unit and Accessories	K190651 ERBECRYO® 2 Cryosurgical Unit and Accessories
Indications for Use Statement - ERBECRYO 2 unit	The ERBECRYO 2 Cryosurgical Unit and Accessories are intended for devitalization (destruction) of tissue during surgical procedures by the application of extreme cold and for removal of foreign bodies, mucous plugs, necrotic tissue, and tissue biopsy by cryoadhesion. Clinical Indications for Cryosurgery: Gynecology: Cervical Erosions, Cervical Polyps, Condylomas, Chronic Cervicitis, Vulva Carcinoma (palliative), Neoplasia Dermatology: Leukoplakia, Fibroma, Condylomas, Basal Cell Carcinoma, Skin Tumor (palliative), Warts, Naephus Ophthalmology: Ablatio Retinae, Glaucoma, Lid Tumor ENT: Leukoplakia, Inoperable Tumor (palliative), Laryngeal Papilloma, Fibroma, Angioma, Haemangioma Thoracic Surgery: Post-Operative Urology: Prostate Tumor (palliative), Condylomas, Penile Tumor (palliative) Phlebology: Varicose Veins of the Lower Limbs (Cryo Stripping) Proctology: Hemorrhoids (1st and 2nd Degree), Pari-Anal Condylomas, Anal Tumor (palliative), Rectal Tumor (palliative), Acute Anal Fissures Pulmonology: Tumors, Granulomatous Tissue, Malignant Lesions (palliative) Pneumology: Tracheobronchial	The ERBECRYO® 2 cryosurgical unit and accessories are intended for cryoadhesion and devitalization (destruction) of tissue by the application of extreme cold.

Characteristics	K151041 ERBECRYO 2 Cryosurgical Unit and Accessories	K190651 ERBECRYO® 2 Cryosurgical Unit and Accessories
Indications for Use Statement - Flexible Cryoprobes	The ERBE Flexible Cryo Probe used with the ERBECRYO 2 Cryosurgical Unit is intended for devitalization (destruction) of tissue during surgical procedures by the application of extreme cold and for removal of foreign bodies, mucous plugs, necrotic tissue, and tissue biopsy by cryoadhesion. Also see Clinical Indications in the ERBECRYO 2 User Manual.	Intended Use / 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.
Prescription or OTC	Prescription	Same
Materials ERBECRYO 2 Unit	Metal sheet, aluminum, copper pipes, plastics and wiring, electronic components	Same
Materials Footswitch	Plastics and wiring	Same
Materials Flexible Cryoprobes	Stainless steel, silicone, aluminum, plastics, brass (gold plated), adhesive	Stainless steel, silicone, plastics, platine, Tyvek, printing color, adhesive
Dimensions of Flexible Cryoprobes	- Outer Diameter (OD) 1.9mm, Length (L) 900mm - OD 1.9mm, L1150mm - OD 2.4mm, L900mm	- OD 1.1mm; L1150mm w/ oversheath OD2.6mm,L817mm - OD 1.1mm; L1150mm w/ oversheath OD2.6mm,L757mm - OD 1.7mm, L1150mm - OD 2.4mm, L1150mm
Units Compatible with Flexible Cryoprobes	ERBECRYO 2	Same

Characteristics	K151041 ERBECRYO 2 Cryosurgical Unit and Accessories	K190651 ERBECRYO® 2 Cryosurgical Unit and Accessories
Other Compatible Equipment	ERBECRYO 2 Cart	ERBECRYO® 2 Cart, VIO Cart
Performance Data of Unit	No. of effect levels: 1 - 5 (depending on instrument)	Same
	Activation: via footswitch	Same
	Cooling gas used: CO_2	Same
	Input Pressure: 653 - 943psi (45 - 65bar)	Same
Provided Condition	ERBECRYO 2 Unit non-sterile, reusable	Same
	Footswitch non-sterile, reusable	Same
	Flexible Cryoprobes non-sterile, reusable	Flexible Cryoprobes sterile, single-use
	All other Accessories non-sterile, reusable	Same
Sterilization Method Used	Steam sterilization for reprocessing reusable Flexible Cryoprobes	Ethylene Oxide (EO) sterilization of single use Flexible Cryoprobes
Shelf Life	Not Applicable for reusable Unit and Accessories	Three (3) years for single use Flexible Cryoprobes

The proposed flexible cyroprobes have comparable technological characteristics compared to the predicate device. The main differences are:

- Outer diameter (two of the proposed flexible cryoprobes have a smaller outer diameter, i.e. 1.1mm and 1.7mm compared to 1.9mm and 2.4mm of the predicate probes).
- The proposed 1.1mm cryoprobe has an additional oversheath compared to the predicate probes.
- The proposed flexible cyroprobes are single-use devices compared to the re-usable predicate device
- The materials of proposed flexible cyroprobes are slightly different compared to the predicate probes

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.

Summary of Biocompatibility Testing

Biocompatibility Testing took place according to standard ISO 10993-1 Fourth edition and in compliance with the FDA guidance document “Use of International Standard ISO 10993-1, Biological evaluation of medical devices”. Cytotoxicity Testing, Acute System Toxicity as well as Sensitization Testing and Testing for Irritation or Intracutaneous Reactivity were carried out with the Erbe Flexible cryoprobes. The probes showed no sensitizing or irritating properties. No release of substances in cytotoxic concentration was observed. Furthermore, the products showed no acute systemic toxic characteristics.

Erbe Elektromedizin GmbH
Traditional 510(k) for ERBECRYO® 2 Cryosurgical Unit and Accessories

Summary of Sterilization Validation

The Erbe Flexible Cryoprobes are provided sterile to the customer and are single use products. Sterilization testing for the flexible cyroprobes was conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile". A mixed load sterilization cycle was validated in accordance with ISO 11135:2014. As requested by the standard a sterility assurance level (SAL) of 10^{-6} was achieved to validate the cycle. Furthermore, levels of residual EO and ECH gas were tested after the sterilization and were within the limits of standard ISO 10993-7:2009.

Summary of Shelf Life Validation

The shelf-life (3 years) of the packed cryoprobes was validated on sterilized samples after transport simulation and accelerated aging and based on the requirements of standard ISO 11607. The samples passed the visual inspection, dye penetration testing, burst test, peel test, bubble emission test, microbial barrier test and the function test.

Standard Testing:

- ANSI AAMI ISO 14971:2007/(R)2010 (Corrected 4 October 2007) Medical devices - Applications of risk management to medical devices
- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- EN 60529 Edition from October 1991 + A1 February 2000 + A2 October 2013 Degrees of protection provided by enclosures (IP Code)
- IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes
- IEC 62366-1 Edition 1.0 2015-02 Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]
- IEC 62366:2007 + A1:2014 Medical Devices - Application Of Usability Engineering To Medical Devices
- IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- EN 1041:2008 + A1:2013 Information supplied by the manufacturer of medical devices
- ISO 11135 Second edition 2014-07-15 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 11737-1 Third edition 2018-01 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product
- ISO 11737-2 Second edition 2009-11-15 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ISO 11607-1 First edition 2006-04-15 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including: Amendment 1 (2014)]
- ISO 11607-2 First edition 2006-04-15 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes [Including: Amendment 1 (2014)]

- DIN EN 556-1:2006 Sterilization of medical devices - Requirements for medical devices to be designated “STERILE” - Part 1: Requirements for terminally sterilized medical devices
- ISO 10993-1 Fourth edition 2009-10-15 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]
- ISTA 2A:2011 Partial Simulation Performance Test - Packaged-Products 150 lb (68 kg) or Less

Summary of Performance Testing

To demonstrate substantial equivalence (performance) testing of the subject device was conducted in accordance with applicable standards, guidance documents and internal design control procedures following 21 CFR 820.30 to ensure that the subject device performs as intended and meets design specifications.

Comparative testing was conducted to determine freezing performance and stability. In addition, comparative *ex vivo* tissue testing on three different tissues (bovine liver, porcine kidney and porcine lung) and animal testing in an *in vivo* porcine lung model was conducted to compare biopsy weight and *in vivo* performance, respectively.

To substantiate the indication “removal of blood clots”, peer-reviewed real world evidence (literature and published case reports) were provided, demonstrating that flexible cryo-technology is a safe and effective method for the removal of airway-obstructing blood clots.
Standard Testing, Biocompatibility Testing, (comparative) performance testing and comparative *ex-vivo* tissue testing demonstrated that the technological characteristics of the proposed device do not raise any new issues of safety or effectiveness. Since the application of the 1.1mm probe is slightly different due to the additional oversheath compared to the predicate device, a benefit-risk analysis was provided to demonstrate that the benefits outweigh the associated risks.

Conclusion:
The intended use/indications for use was simplified as well as clarified for the proposed ERBECRYO® 2 Cryosurgical Unit, but the proposed unit has the same intended use, principles of operation, technological characteristics, as well as performance characteristics as the predicate Cryosurgical Unit in the previously cleared 510(k).

The differences between the proposed and the predicate cryoprobes mentioned above do not raise different questions of safety and effectiveness and the functionality of both groups has been found to be comparable. The principles of operation and technological characteristics are equivalent. Validation and verification activities in design control that include testing/certification to designated standards and performance/bench testing of the proposed cryoprobes has demonstrated the subject device is substantially equivalent to the predicate device. The ERBECRYO® 2 Cryosurgical Unit and Accessories subject device is as safe and effective as the predicate device.