DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 4, 2015

ERBE USA Incorporated
% Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street, North West
Buffalo, Minnesota 55313

Re: K151041
Trade/Device Name: ERBE 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: March 26, 2015
Received: April 20, 2015

Dear Mr. Job:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151041

Device Name

ERBE ERBECRYO 2 Cryosurgical Unit and Accessories

Indications for Use *(Describe)*

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 Stenoses (Cryo re-canalization)

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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K151041

510(k) Summary

Submission Information

Trade (Proprietary) Name:	ERBE ERBECRYO 2 Cryosurgical Unit and Accessories
Common Name:	Cryosurgical Unit & Accessories
Owner/Submitter:	ERBE USA Incorporated 2225 Northwest Parkway Marietta, GA 30067 Phone: 770-955-2577 Fax: 770-955-2577
Contact Person:	John Tartal, QA/RA Director
CFR Classification:	Cryosurgical Unit & Accessories (21 CFR 878.4350)
Panel:	General and Plastic Surgery
Product Code:	GEH
Type of Submission:	Traditional 510(k)
Date of Summary:	March 2015
Predicate device:	ERBE ERBOKRYO® CA and Accessories; K051509

Device Description

The ERBECRYO 2 Cryosurgical Unit and Accessories consists of a cryosurgical unit, probes with a cryosurgical tip, a connecting hose to be connected to a CO_2 (Carbon Dioxide) gas bottle and a footswitch for activation. The system is mounted on a cart, which also carries up to two CO_2 gas bottles.

The ERBECRYO 2 Cryosurgical Unit and Accessories is used to apply extreme cold to tissue during surgical procedures. The system uses the Joule-Thomson principle where pressurized gas expands through a fine orifice inside the tip of the cryosurgical probe producing a rapid drop in temperature and freezing the probe tip and the surrounding tissue.

The unit and accessories are provided non sterile. The cryoprobes are reusable and directions for cleaning and sterilizing the cryosurgical probes are provided in the Notes on Use.

Design and materials of the ERBECRYO 2 Cryosurgical probes are very similar to the predicate probes.

Intended Use/ Indications for Use

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 (1^{st} and 2^{nd} Degree), Pari-Anal Condylomas, Anal Tumor (palliative), Rectal Tumor (palliative), Acute Anal Fissures
Pulmonology:	Tumors, Granulomatous Tissue, Malignant Lesions (palliative)
Pneumology:	Tracheobronchial Stenoses (Cryo re-canalization)

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

Similarities: The ERBECRYO 2 Cryosurgical Unit and Accessories has the same basic technology characteristics as the predicate unit and accessories to induce extreme cold to tissue, and the indications for use are the same. Both the proposed and the predicate cryosystems use CO_2 gas and are closed systems.

The probes for the proposed and predicate cryosurgical units have the same construction, a similar design and similar materials.

Differences: The following features are new in the proposed ERBECRYO 2 Cryosurgical Unit:
- The pressure and flow sensors and valves are controlled electronically
- Pressure readings are shown in the interactive display.
- The 6 soft keys and the monochrome graphical display provide information to the user and enable user interaction.
- Timer function for cryoactivation
- Program memory
- Counter for number of reprocessing actions of probes
- Additional low setting (E1). With the default setting (E2), which is equivalent to the performance of the predicate system, the freeze is performed within 2-3 sec (900 mm probes). The low setting gives an option of a “milder freeze”.
- Not suitable for operation with N_2O gas

- 2 gas bottles with a switch over connector mountable on the system cart (optional) versus one gas bottle in the predicate system.

In contrast the predicate cryosurgical unit operates purely mechanically, without software control, has no interactive display except for a manometer reading of the inlet gas pressure.

The following features are new in the proposed ERBECRYO 2 Cryosurgical probes:
- Different shape and design connector to the cryosurgical units
- The connector contains an EEPROM for instrument recognition
- Cap for closing of the plug during reprocessing is fixed to the plug
- Additional 1050 mm probe (predicate probes are 900 mm length)

Physical and Performance Testing

Physical and performance characteristics of the ERBECRYO 2 Cryosurgical system are comparable to those of the predicate system, as is shown in bench testing.
The system conforms with the following standards:

EN ISO 14971:2009 Application of Risk Management to Medical Devices

ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

AAMI / ANSI / IEC 60601-1-2: 2007, Third Edition, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

IEC 60601-1-6: 2010 Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability

EN 62366: 2008 Medical Devices Application of Usability to Medical Devices

EN 62304: 2006 Medical Device Software - Software Life Cycle Processes

EN ISO 10993-1: 2010 Biological evaluation of medical devices Part 1: Evaluation and testing.

EN ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity

EN ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity (Biocompatibility)

EN ISO 17664: 2004 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of re-sterilizable medical devices.

EN ISO 15223-1:2012 Medical Devices – Symbols to be Used with Medical Device Labels, Labeling and Information to be Supplied – Part 1: General Requirements

EN 1041:2008 Information Supplied by the Manufacturer of Medical Devices

No studies in the living animal have been performed. As performance and safety testing were done as bench testing and the surgical application of cryotechnology is well established, the applicant does not consider it necessary to perform testing in the living animal. The intended use was validated in comparative tissue studies against the predicate system. The performance was similar for both systems.

Conclusion

The Proposed Device, the ERBECRYO 2 Cryosurgical System and Accessories, is a further development of the ERBOKRYO CA Cryosurgical System and Accessories cleared with K051509. The predicate device, ERBOKRYO CA, is a simple supply unit, which does not control the gas flow or application time and does not give the user any possibilities for different settings. Software has been added to the proposed model, ERBECRYO 2, to control these parameters.

In summary the proposed and predicate systems essentially differ in the software added to the proposed system to control gas flow and pressure and record the application time. These parameters are shown in the new interactive display.

Therefore the proposed system provides state of the art technology and a safer use and there are no new issues, which could raise concern for safety and efficacy with the ERBECRYO 2 Cryosurgical Unit and Accessories.