K972269

510(k) Notification ERBE Disposable Patient Return Electrode

June 13, 1997

Summary of Safety and Effectiveness

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This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

For more than 50 years, high-frequency (HF) surgery has been used to cut and/or coagulate biological tissue using the intrinsic thermal effect of electric current. ERBE has been working intensively during this entire period in the production and distribution of state-of-the-art HF surgical instruments and accessories. The ERBE Disposable Patient Return Electrodes are a key accessory in the efficacious application of HF surgical instruments and are intended to be used primarily with Erbe's range of Electrosurgical Generators but they are also compatible with generators from other manufacturers.

The Erbe electrodes and are to be sold with and without a pre-attached cable. Erbe will offer the Return Electrodes without the pre-attached cable as these provide the user the option of purchasing a less expensive item and utilizing a re-usable cable.

Disposable return electrodes have been manufactured and distributed worldwide by Leonhard Lang GmbH and the ERBE Disposable Return Electrodes utilize the same materials and technology. There are no known adverse reactions or field problems with electrodes utilizing this technology or materials

It is Erbe's intention to apply for ISO Registration and market this product under the CE mark. It is Erbe policy that all product marketed under the Erbe name are so registered.

Based upon the documents enclosed in this Notification, we believe the ERBE Disposable Patient Return Electrodes are Safe and Effective for their intended purpose when used in accordance with the Instructions for Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Erbe USA, Inc.
c/o Mr. Michael A. Clark
South East Regulatory Associates, Inc.
1070 Thornwood Lane
Dacula, Georgia 30211-3007

Re: K972269
ERBE Disposable Patient Return Electrode
Regulatory Class: II
Product Code: GEI
Dated: June 13, 1997
Received: June 17, 1997

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Dear Mr. Clark:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to

comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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June 13, 1997

INDICATIONS FOR USE

ERBE Disposable Patient Return Electrodes are Indicated for Use only in conjunction with Electrosurgical Generators for cutting and coagulation of human tissue.

The Electrodes are for use with Generators with Return Electrode Safety Systems (divided contact surface) and Generators without Return Electrode Safety Systems (single contact surface).

The Electrodes must be applied as close as possible to the operative site, preferably on the thigh or upper arm of the patient, and must not be applied to scars, infected skin, bony protrusions, or over metal implants.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972269

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)