

Amendment to: 510(k) Notification K933157 Erbotom ICC 200

July 21, 1993

2/23/94

MICHAEL A CLARK
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SOUTH EAST REGULATORY ASSOCIATES

Summary of Safety and Effectiveness

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 of state-of-the-art HF surgical instruments. The ICC 200 represents one of the latest of these instruments. It is based upon ERBE's aim of continuous improvement in the application of HF surgical instruments and the quality and safety of cutting and coagulation of biological tissue.

ERBE has successfully marketed the FDA approved ACC 450 unit. The ICC 200 is designed and constructed utilizing the same technical features as the ACC 450.

In common with all ERBE equipment, the ICC 200 will carry TUV and UL approvals prior to introduction into the marketplace. ERBE's HF surgical instruments are all equipped with safety devices to protect both the patient and user against inadvertent injury.



Michael A. Clark



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 23 1994

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

Erbe USA, Inc.
c/o Mr. Michael A. Clark
South East Regulatory Associates
775 Oxford Hall Drive
Lawrenceville, Georgia 30244

Re: K933157
Erbotom ICC 200
Regulatory Class: II
Dated: November 19, 1993
Received: November 22, 1993

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

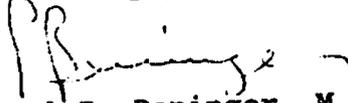
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the

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labeling for your device, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-326) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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