



DEPARTMENT OF HEALTH & HUMAN SERVICES

D1368B
HFI-35
Public Health Service
Food and Drug Administration

CINCINNATI DISTRICT OFFICE
1141 Central Parkway
Cincinnati, OH 45202-1097

January 28, 1998

WARNING LETTER
CIN-WL-98-92

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Richard A. Auhill, President
Circon ACMI
6500 Hollister
Santa Barbara, CA 93111-3019

Dear Mr. Auhill:

The Cincinnati District of the Food and Drug Administration (FDA) conducted an inspection in November 1997, of your Norwalk, Ohio, facility. The inspection covered the AEH-3 Electrohydraulic Lithotripter and E-1F Sterile Probe (an accessory).

The products are considered to be medical devices under the Federal Food, Drug and Cosmetic Act (the Act) because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. The Act requires that manufacturers of medical devices obtain marketing clearance for their products from FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

The Lithotripter Generator (AEH-3) and Probe (E-1F) are misbranded within the meaning of Section 502(o) in that a notice or other information respecting the devices was not provided to the FDA as required by Section 510(k) of the Act.

Until your firm receives notice from the Center for Devices and Radiological Health clearing the device for commercial distribution, the Lithotripter Generator (AEH-3) and Probe (E-1F) are adulterated within the meaning of Section 501(f)(1)(B) of the Act, in that it is a Class III device under Section 513(f) and does not have an approved application for premarket approval in effect pursuant to Section 515(a) or an approved application for an investigational device exemption under Section 520(g).

In the reply letter of November 13, 1997, to Investigator Kathryn McCarty, Mr. Ervin Taylor acknowledges that Circon has not applied for a premarket notification, and states that one is not required because Lithotripter Generator (AEH-3) is a preamendment device. Mr. Taylor stated in paragraphs 1 & 2 that Circon ACMI was a distributor during 1981 and 1982 of the Northgate SD-1 Lithotripter, and in 1983 (par. 3) your firm contracted with a firm named [REDACTED] to manufacture a copy of the Northgate Lithotripter to be labeled as an American ACMI product. At that point, your firm became an initial manufacturer (specification developer) which commercially offered for sale a device after May 28, 1976, the

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enactment date of the medical device amendments. Therefore, you can not claim this device to be preamendment. A new manufacturer of a device is required to obtain a 510(k) regardless of whether they would have all of the proprietary information of the original manufacturer. [REDACTED] may have made an exact copy of the Northgate Lithotripter; however, we consider a device manufactured and marketed by another firm after May 28, 1976, to be a new device requiring a 510(k).

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this into account when considering the award of contracts. Also, no requests for Certificates for Products of Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct this deviation. Failure to promptly correct this deviation may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office within 15 days of receipt of this letter, of the specific steps you will be taking to comply with our request.

Your response should be sent to Lawrence E. Boyd, Compliance Officer, Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio, 45202.

Sincerely,



Diana J. Kolaitis
District Director
Cincinnati District

LEB/pjk

cc: Circon ACMI
c/o John Trushel, Vice-President, Manufacturing
93 North Pleasant Street
Norwalk, OH 44857

Circon ACMI
c/o Ervin F. Taylor, D.E. Director, Regulatory Affairs and Quality Assurance
and David Zielinski, Vice-President, General Manager
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