

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

FIRM NAME

Official Correspondent/or individual named in 510(k) submission

FIRM'S COMPLETE ADDRESS

Dear: _____ :

Your firm has been identified as having submitted a premarket notification submission for a transilluminator device and/or having listed these products with the Agency. The Food and Drug Administration (FDA) is, by this letter, notifying you that it considers transilluminators labeled or represented for the clinical evaluation of the breast to violate Sections 502(a) and 502(f) of the Federal Food, Drug, and Cosmetic Act (the Act).

Transilluminators labeled or represented for clinical evaluation of the breast are misbranded within the meaning of Sections 502(a) and 502(f) of the Act, in that the labeling is false or misleading and fails to bear adequate directions for use since transillumination is not adequate and effective for clinical use in the detection and diagnosis of breast disease, particularly early breast cancer.

You may be aware that the National Cancer Institute recently issued a Cancer Facts Communication entitled, "TRANSILLUMINATION

NOT EFFECTIVE FOR EARLY BREAST CANCER DETECTION" (copy enclosed).

In addition the American Cancer Society's policy on Breast Cancer Detection Techniques, states that diaphanography (transillumination) is not of sufficiently proven value to be used routinely to detect breast cancers which are too small to be found by physical examination.

FDA's Obstetrics and Gynecology Devices Advisory Panel also recently considered the safety and efficacy of breast transilluminators. This expert panel concluded that these devices do not provide meaningful clinical information and should not be used in the clinical evaluation of breast tissue, either alone or in conjunction with other techniques, and should be restricted to use in an approved clinical investigation.

We request that you take prompt action to assure that the products you distribute are in compliance with the above labeling requirements and all other requirements of the Act. This includes the requirement to register and list and to conduct clinical investigations in accordance with the investigational device exemptions (IDE) regulations (21 CFR Part 812). Failure to promptly correct any such violations can result in regulatory action without any further notice to you. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to

bring your products into compliance with the Act. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance and Surveillance
Division of Compliance Operations (HFZ-322)
1390 Piccard Drive
Rockville, Maryland 20850.

Sincerely,

William H. Damaska

Director

Division of Compliance Operations

R/D:5/22/91:KStutsman

redrafted:12/16/91

A. Companies identified as having submitted 510(k)s for breast transilluminators:

1. Mr. Kenneth J. Durbin
Vice President

CaVaDa, Inc.
5100 Northwest 12 Avenue
Fort Lauderdale, Florida 33309

Source: 510(k) K803253 submitted 12/23/80
(NOTE: firm has not registered or listed)

2. Mr. Ronald A Haverl
President
Spectrascan Inc.
200 Day Hill Road
Windsor, CT 06095

Source: name and title - 510(k) K812275 submitted 8/13/81
address - provided in 11/16/81 Listing form
(NOTE: firm is not registered)
(NOTE: 124 Hebron Avenue, Glastonbury,
Connecticut 06033 address provided in 510(k))

3. Mr. Philip Colman
President
Infrared Imaging Corporation
13210A Fiji Way
Marina del Rey, California 90291

Source: 510(k) K812614 submitted 9/15/81
(NOTE: firm has not registered or listed)

4. Mr. Gary D. Lewis
President
Somanetics Corporation
1241 Chicago Road
Troy, Michigan 48083

Source: Registration - last updated 4/18/91
(NOTE: firm has not listed)

5. Ms. Linda B. Grable
President
Lintronics International Ltd. Inc.
1660 NW 65 Ave.
Plantation, FL 33313

Source: 9/90 EIR

6. Jack Cantwell, Inc.
c/o Medical Device Consultants, Inc.
Attn: James R. Veale
Vice President, Regulatory Services
45 West Street, Suite 2
Attleboro, Massachusetts 02703

Source: 510(k) K904029 submitted 8/31/90

B. Companies identified by Registration & Listing Branch -- as having listed under product codes HJM (transilluminator, AC-powered), HJN (transilluminator, battery powered), and ETJ (transilluminator). These firms may be distributing general purpose transilluminators or specific use transilluminators. (NOTE: this list does not include several foreign firms for which addresses were not available, a firm listed as out of business, and a firm listed as tentatively out of business as of 1987.)

7. Mr. Ed Neumueller
General Manager
Radiation Measurements Incorporated
2500 W. Beltline Hwy.
P.O. Box 327
Middleton, Wisconsin 53562-0327

8. Mr. John Watkins
Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, NY 13153-0187

9. Mr. Anthony J. Newson
Quality Assurance Manager
Downs Surgical Ltd.
Parkway Close, Parkway
Industrial State, Sheffield
South Yorkshire, United Kingdom
S94WJ

10. Mr. James G. Fedorka
Sylvan Corporation
612 Cedar Street
Irwin, PA 15642

11. Mr. Anthony J. McAndrews
Electro Surgical Instrument Co., Inc.
37 Centennial Street
Rochester, NY 14611

The American College of Radiology's Policy Statement on Breast Cancer Screening Centers recognizes that transillumination is not sufficiently sensitive to substitute for mammography for breast cancer.