Everette C. Burdette, Ph.D.
President
Labthermics Technologies, Inc.
701 Devonshire Drive
Champaign, Illinois 61820

Sep 29 1989

Re: P880062
SONOTHERM® 1000 Ultrasound Hyperthermia System
Filed: August 8, 1988
Amended: January 5, May 17, June 2, September 6, 15, and 21, 1989

Dear Dr. Burdette:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the SONOTHERM® 1000 Ultrasound Hyperthermia System. This device is indicated for combined use with radiotherapy in the palliative management of certain solid surface or up to 8 cm deep malignant tumors (i.e. epidermal [melanoma], carcinoma [squamous cell, nonsquamous cell, large cell, infiltrating ductal, transitional cell, and adenocarcinoms], sarcoma, or schwannoma) that are either candidates for an initial course of radiotherapy or are recurrent or progressive despite conventional therapy. The PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (act) under authority of section 515(d)(1)(B)(ii) of the act. The device is further restricted within the meaning of section 520(e) under the authority of section 515(d) (1) (B)(ii) insofar as the approved labeling specifies the requirements that apply to the training of physicians who may use the device.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. In addition, the notice will state that a copy of all approved labeling (which may be a draft of the final labeling) is available for public inspection at CDRH. Within 30 days of publication of
the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

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All required documents must be submitted in triplicate, unless otherwise specified, to the address below and shall reference the above PMA number to expedite processing:

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
1390 Piccard Drive
Rockville, Maryland 20850

If you have any Questions concerning this approval order, please contact Ms. Kathy Poneleit at (30l) 427-1050.

Sincerely yours,
Robert l. Sheridan
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure