Exhibit 16

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John Brenna
President
Computerized Thermal Imaging, Inc.
1719 West 2800 South
Ogden, Utah 84401

Re: P010035
CTI™ BCS 2100
Filed: June 15, 2001
Amended: August 22, September 10, November 6, 2001, and February 28, May 29, June 27, November 12 and 26, 2002.

Dear Mr. Brenna:

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).

The Radiological Devices Advisory Panel, which also reviewed your PMA, recommended to CDRH at the December 10, 2002, Panel meeting that the PMA be considered not approvable. We regret to inform you that CDRH concurs and has determined that your application is not approvable based on the requirements of 21 CFR 814.44(f), which also requires FDA, where practical, to identify measures necessary to make the PMA approvable.

The major flaw in your PMA concerns the clinical trial and the manner in which the results were analyzed. The key issues include the following:

a) Your proposed indications for use (IFU) were revised (i.e., restricted to women with masses visible on mammography) on the basis of a retrospective analysis of the results of your clinical study in the original PMA dated June 15, 2001, thereby limiting further use of the PMA results for the purpose of supporting the proposed new IFU.

b) The added clinical data from 69 of 275 subjects in the "post-PMA" (PPMA) are insufficient by themselves (i.e., too few subjects) to constitute an adequate study. Combining the PPMA data with the original PMA data, employing the Bonferroni correction, is statistically inappropriate in the absence of multiple formal hypotheses. (It should be noted that even if the Bonferroni correction to the sensitivity confidence interval were valid, it would place the lower confidence limit on the sensitivity too low for an acceptable risk/benefit ratio.)

c) The basis for enrollment was not consistent with the final proposed IFU. That is, enrollment was not limited to mammographically visible masses.

d) The number of exclusions of enrolled subjects was excessive – well over 50%.

In summary, the results of your clinical study do not demonstrate that there is reasonable assurance that your device is safe and effective for your proposed IFU.

To place your PMA in approvable form, you should do the following:

1. Perform a new, focused premarket clinical study in which you clearly define the target population for the device, and strictly adhere to this definition for the enrollment of subjects.

2. Before beginning your new study, consider revising the IFU (in particular, the target population) based on exhaustive data mining of the PMA/PPMA database. However, whether or not you revise the IFU, the new clinical study must reflect whatever IFU you choose for the device.

3. Perform a reproducibility study that takes into account the variations that may be encountered in clinical practice. This should include such things as patient positioning, room temperature, different technologists, different radiologists (ROI selection variances), menstrual cycle, etc.

4. Provide a validated quality assurance procedure that the user can perform on a daily basis to ensure that the device is performing properly. Include instructions for corrective action if it is not.

In your new clinical study we suggest the following:

- Avoid, insofar as possible, the subsequent exclusion from analysis of enrolled subjects. In general, no more than 15% of enrollees should ever be excluded from final analysis in a clinical study, and the exclusions should be explained as well as possible.

- In addition to averages, provide data from each individual radiologist in order to permit estimation of intra- and inter-reader variability. Provide such variability analyses.

- Patients entering the study should have already had a complete diagnostic work-up, including such examinations as ultrasound, etc., whenever these are clinically appropriate. Maintain and provide records of the complete work-up of the subjects from first exam through final biopsy results.

- State your sensitivity and/or negative predictive value (NPV) hypothesis(es) clearly.

- If the device is intended only for mammographic masses, we suggest that you consider reestablishing the IOS threshold, based on masses only.

- Review your new protocol with FDA.

The deficiencies given above reflect the issues that we believe need to be resolved before our review of your PMA application can be completed. In developing the deficiencies we carefully considered the statutory criteria as defined in Section 515 of the Federal Food, Drug, and Cosmetic Act for determining reasonable assurance of safety and effectiveness of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the document entitled "A Suggested Approach to Resolving Least Burdensome Issues." It is available on our Center webpage at: http://www.fda.gov/cdrh/modact/leastburdensome.html

This is to advise you that an amendment including the above requested information will be considered a major amendment and may extend the FDA review period up to 180 days. As provided by 21 CFR 814.37(c), you may decline to submit a major amendment requested by FDA in which case the review period may be extended for the number of days that elapse between the date of such request and the date that FDA receives the written response declining to submit the requested amendment.

As provided by 21 CFR 814.44(f), you may amend your PMA as requested above, withdraw the PMA, or consider this letter to be a denial of approval of the PMA under 21 CFR 814.45 and request administrative review. Any request for administrative review, either through a hearing or review by an independent advisory committee, under section 515(d)(4) and 515(g) of the Federal Food, Drug, and Cosmetic Act, must be submitted in the form of a petition for reconsideration under 21 CFR 10.33 and in accordance with the general administrative procedures under 21 CFR 10.20. Any petition for reconsideration must be submitted to the Food and Drug Administration, Dockets Management Branch (HFA-305), Room 1061, 5630 Fishers Lane, Rockville, Maryland 20852, within 30 days of your receipt of this letter. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issues to be reviewed, the form of the review to be used, the person may participate in the review, the time and place where the review will occur, and other details.

As provided under 21 CFR 814.44(g), FDA will consider this PMA to have been voluntarily withdrawn if you fail to respond in writing within 180 days of the date of this request for a PMA amendment. You may, however, amend the PMA within the 180-day period to request an extension of time to respond. Any such request is subject to FDA approval and should justify the need for the extension and provide a reasonable estimate of when the requested information will be submitted. If you do not amend the PMA within the 180-day period to (1) reflect the above suggestions, or (2) request an extension of time to respond and have the request approved, any amendment submitted after the 180-day period will be considered a resubmission of the PMA

and will be assigned a new number. Under these circumstances, any resubmission will be given a new PMA number and will be subject to the requirements of 21 CFR 814.20.

You may amend the PMA to provide the above requested information (10 copies), voluntarily withdraw the PMA (3 copies), direct CDRH to complete processing the PMA without the submission of additional information or request an extension.

The required copies of the amended PMA should include the FDA reference number to facilitate processing for this PMA and should be submitted to the following address:

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd
Rockville, Maryland 20850

If you have any questions concerning this not approvable letter, please contact Robert J. Doyle at (301) 594-1212.

Sincerely yours,

Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health