Exhibit 5

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 10 2002

Mr. John Brenna
President
Computerized Thermal Imaging, Inc.
476 Heritage Park Blvd., Suite 210
LAYTON UT 84041

Re: P010035
CTI™ BCS 2100
Filed: June 15, 2001
Amended: August 22, September 10, November 6, 2001 and February 28, 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).

We regret to inform you that the PMA must be considered not approvable. Based on the requirements of 21 CFR 814.44(f), FDA, where practical, must identify measures necessary to make the PMA approvable. Accordingly, to place your PMA in approvable form, you must amend it to include the following:

1. The results for cancers represented mammographically by either masses or architectural distortion are more favorable to device effectiveness when those represented by calcifications alone are omitted from the analysis. This constitutes after-the-fact selection of data, and, as such, the results for masses and architectural distortion need to be confirmed in a second trial to rule out that these results were due merely to stochastic noise.

2. The finding that depth of the masses within the breast does not affect the device Se/Sp is counterintuitive. It is difficult at best to estimate the depth of a lesion from two mammographic views separated by an unknown viewing angle and each with its own compression, and the counterintuitive nature of this finding for the masses may simply reflect inaccuracies of the depth determinations and again represent stochastic noise. Please provide the data from your second clinical trial to confirm your original findings with regard to the depth of the mass within the breast. This time, however, we would suggest using ultrasound to determine lesion depth, as ultrasound is more accurate than mammography for this purpose.

3. While it accords with intuition that the IOS is greater for larger malignant masses, it is somewhat surprising that the opposite is the case for benign masses. This should be

confirmed, in a second clinical trial, since this inverse relationship between IOS and benign mass size contributes to the ability of the device to separate benign from malignant masses.

4. You found that the denser the surrounding normal tissue the greater the IOS for malignant masses, but you found that the opposite occurs for benign masses. Please explain this finding for benign masses, or at least confirm this result with a second clinical trial.

5. In the table in your answer to our question 3 of September 5, 2001, the last column gives the results for AVGSPEC94 (the average specificity for sensitivities greater than or equal to 0.94). In considering the two rows for LOS1 and IOS+LOS1 we note that there is significant overlap of these two confidence intervals, yet the difference (bottom row) has a much smaller variance with a confidence interval that excludes zero. In other words, you found a statistically significant enhancement of ROC performance when the device is use adjunctively with mammography. However, the exclusion of zero is surprising given the degree of overlap. Please check this result, and if confirmed, explain why there is such a high degree of correlation between LOS1 and IOS+LOS1 (the only way that this result could be accurate). Also please provide us with the raw data to check the calculation of the confidence intervals.

The deficiencies identified above represent 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 "A Suggested Approach to Resolving Least Burdensome Issues" document. 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)(3) 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) correct the above deficiency(ies), 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 (three 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 John Monahan at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Reproductive Devices
Office of Device Evaluation
Center for Devices and Radiological Health