EXHIBIT 21

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April 8, 2003

Daniel G. Schultz, M.D.
Director, Office of Device and Evaluation
Food and Drug Administration
9200 Corporate Blvd. HFZ-400
Rockville, MD 20850

Dan,

As we discussed during our teleconference yesterday, CTI is prepared to perform additional analyses of existing clinical data to strengthen the body of evidence supporting the effectiveness of the BCS2100 for its proposed indication. CTI has carefully reviewed the panel proceedings and discussions from the FDA review staff to determine appropriate targets for these analyses. Based on this review, CTI has identified, and is prepared to address through analysis of existing data, the following six target areas.

1. **Overall Device Efficacy for All Lesion Types:** The FDA recently informed CTI that it considered the BCS2100 to be ineffective for the overall study population of all lesion types. CTI believes that the BCS2100 is effective for all lesion types and could provide new analysis results to demonstrate this overall device effect.

2. **Descriptive Statistics and Plots Illustrating Reader-to-Reader Variability:** CTI's most recent PMA submissions did not provide any analysis results directed at characterizing reader-to-reader variability. CTI could provide a device performance characterization for each reader and a descriptive assessment of reader-to-reader variability in performance.

3. **More Sophisticated Efficacy Analysis:** The analysis procedures used to estimate sensitivity and specificity in CTI's PMA submissions to date did not incorporate dependencies between multiple lesions within a subject and multiple readings of a single lesion by different readers. CTI could perform a more sophisticated analysis of sensitivity and specificity that formally incorporates these dependencies as well as other variance components such as reader-to-reader variability. The products of this more sophisticated analysis would include confidence intervals for sensitivity and specificity that are valid with respect to the dependencies mentioned above and a quantitative estimate of the magnitude of reader-to-reader variability to complement the descriptive results discussed under Item 2.

4. **Lack of Bias Associated with Excluded Cases:** In response to FDA inquiries about the potential for bias associated with excluded cases, CTI performed a number of analyses comparing included and excluded cases, and reported the results of those analyses in Amendment 7. If the bias associated with excluded cases remains a concern, CTI could perform additional comparative analyses.

5. **Resolution of Root Causes of Excluded Cases:** In Amendment 7, CTI carefully documented each excluded case and detailed categories of exclusions and the numbers of cases falling into each category. CTI could divide these excluded cases into unresolved and resolved classes to characterize the expected rate at which the device would yield useful clinical information in actual practice.

6. **Efficacy Analysis with Bonferroni Correction:** The FDA has insisted that the Bonferroni correction is an unacceptable method of data analysis to be applied in the case of the BCS2100. CTI has researched this scientific issue at some length and has concluded that the scientific literature, including a primary reference cited by FDA staff and authored by FDA staff not involved in the BCS2100 PMA review, support the use of the Bonferroni correction in just the manner that CTI has employed it. CTI would welcome the opportunity to resolve this issue and jointly determine an appropriate number of subgroups to employ when using the Bonferroni method to correct the confidence intervals for sensitivity and specificity.

CTI resources for additional data analysis are scarce. The company must ensure that all further analyses of existing data are efficiently and specifically targeted to address outstanding issues that, when resolved, will contribute to the approvability of PMA P010035. It is imperative that the FDA provides input into this process.

Therefore, as also discussed during our teleconference yesterday, I am requesting that you arrange a meeting as soon as possible to include all relevant FDA staff and CTI representatives. The purpose of this meeting would be to identify any and all re-analysis activities that have good potential to move the BCS2100 PMA approval process forward. These re-analysis activities need not be limited to those identified above. Please contact me at your earliest convenience to arrange the details of this meeting.

I would also like to remind you of CTI's recognition that a post-approval study would strengthen the evidence for the effectiveness of the BCS2100 in the proposed target population. CTI believes that it would be in both the FDA's and the company's interest to conduct such a post-approval study and would welcome the opportunity to plan such a study in consultation with the FDA. I can be reached at 203-722-4245 for further discussion.

Sincerely,

John M. Brenna
Computerized Thermal Imaging
President and COO