Exhibit 20

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2003

RECD MARCH 24TH '03

Mr. John M. Brenna
President and COO
Computerized Thermal Imaging, Inc. (CTI)
1719 West 2800 South
Odgen, Utah 84401

Dear Mr Brenna:

Your letter dated January 27, 2003, to Commissioner McClellan has been referred to me for response. As Deputy Director of the Center for Devices and Radiological Health (Center), I have oversight responsibilities for policies and procedures involving each of the Center's five offices, including the Office of Device Evaluation (ODE). In preparing this response, I have reviewed portions of the administrative record relating to CTI and have had discussions with members of the ODE management staff. We are now in receipt of a second letter from you dated March 6, 2003, and, given the timing of that letter and the similarity of issues raised, I will use this opportunity to respond to that correspondence as well.

Let me begin by saying that the Center's responsibility as part of a public health agency is to provide a reasonable assurance of the safety and effectiveness of medical devices intended for use in the United States, and safety and effectiveness must be based on valid scientific evidence. Having said that, we also recognize the importance of having a fair and objective process for evaluating medical devices and making our regulatory determinations, and thus, we take very seriously your concerns regarding the way in which the CTI submission was handled.

Diagnosis and treatment of breast cancer is one of the nation's major public health concerns, and efforts toward earlier detection and diagnosis are among the Agency's top priorities. Although we agree that a reduction in the number of biopsies of lesions that turn out to be benign is an important outcome, we believe there must be adequate assurance that the diagnosis of women with potentially curable malignancies will not be delayed. We are very interested in the development of safe and effective devices to improve the diagnostic accuracy of mammography. We believe we have worked with your firm interactively toward this end in our review of your PMA, and we are prepared to continue doing so. We hope we can resolve misunderstandings between your firm and the Agency in order to move forward on this important topic.

The central issue from the Agency's perspective is the validity of the data, as currently presented, to predict the performance of CTI's device in the target population proposed in your PMA submission with a degree of certainty commensurate with the critical importance of the decision-making process affected

by its use, that is, when a woman with a suspicious breast lesion should go on to biopsy. We recognize that, given the novel nature of this technology, it was impossible to predict prior to clinical evaluation how the device would perform in various clinical circumstances. We also agree that the results obtained in your clinical trial showed great promise for the ability of the device to discriminate benign from malignant lesions in those women with mammographically detected masses, and may, in fact, demonstrate broader applications over time. We cannot, however, overlook the fact that your data showed exceedingly wide confidence intervals for your sensitivity calculations, a subject exclusion rate exceeding 50%, and statistical analyses that were not appropriate for the circumstances in which they were used. These concerns with the current data are the basis for our determination that your PMA is not approvable at this time.

Regarding the concerns you have raised about the review process for your premarket approval application (PMA) P010035, I would like to make some general comments and then address some of the specific points presented in your letters. Let me assure you that the Center does not view any mistakes it may have made with respect to the review process as harmless errors. ODE management acknowledged that the delay in identifying the Center's concerns regarding the amendment submitted in response to the first not approvable letter was a serious matter which had significant impact not only on the company but on the effectiveness of the review process as well.

Some of the statements in your letter suggest that a Center decision to schedule a panel meeting is an indication that some or all reviewers have concluded the product is effective. The Agency does not determine if a device is safe and effective until we have had an opportunity to completely review all the data submitted by the firm, as well as the recommendations of the panel. In retrospect, I believe some of the problems your firm experienced during this process were the result of ODE's efforts to expedite review of this novel technology by scheduling the panel meeting as early as possible and subsequently concluding that there were significant issues with the data submitted in your amendment. The Center is currently reviewing the way it schedules panel meetings and communicates with sponsors regarding the role of the panel meeting in the review process.

It is my understanding that the panel meeting's postponement was an administrative decision mutually agreed upon by the Agency and your company. This postponement allowed time for CTI, as well as the Center, to adequately prepare for the meeting in light of the issues raised at the October 1, 2002, meeting between CTI and the Agency. Once the postponement decision was reached, we attempted to communicate to your company as quickly and clearly as possible the outstanding issues and to obtain feedback from your company to assure that there was mutual understanding of those issues. In fact, a significant number of issues were resolved during those interactions and were not brought to the panel for review.

Your correspondence also expresses concern that FDA "leaked" information about postponing the panel meeting. Information about rescheduling the panel meeting was not "leaked," but rather, was given out by the Agency on the advisory committee information line (referred to in your letter as a "hotline") in an effort to avoid having someone make an unnecessary trip to Washington only to learn that the meeting had been postponed. It was accurate and consistent with meeting information normally provided by the Agency in advance of a panel meeting. Unfortunately, the phone line information was processed before program managers in the Center could communicate to front line staff our agreement with CTI that we would coordinate the timing of the postponement announcement with your firm. I apologize for this. We did, however, coordinate the content of the formal announcement (i.e., our letter of October 9, 2002) to reflect the fact that both the company and the Agency agreed that additional time was needed to achieve a fair and balanced meeting.

The next series of issues that you raised reflect your belief that there was a bias against your device on the part of members of the ODE review staff and that the review memoranda and panel presentations reflected that bias. I do not believe that the issues raised in the review of your device indicate bias. First, it was normal procedure for FDA to provide review memoranda to the panel prior to the meeting. Second, the issues raised in the review of your device are a reflection of an honest scientific debate. It is part of FDA's responsibility to question and analyze data provided to us by the medical device industry and its consultants. Not infrequently, those analyses yield a modified, or in some cases, a very different conclusion than that reached by the sponsor. This is a healthy and necessary part of the clinical and scientific review process. It is for this very reason that we believe it is critical to enlist outside experts to help us address difficult questions and contribute to our goal of reaching a sound scientific and regulatory decision. Although I understand your position that some of the comments and concerns raised in the memoranda and presentations were contrary to your own interpretation of the data and detrimental to your desire to have the submission approved, I can assure you that the not approvable decision was based on a thorough review of all the data and opinions, including those of the individual panel members expressed at the meeting and in written correspondence to the Agency.

Regarding your observations related to the constituency of the panel and the conduct of the meeting, let me address each of those issues in turn. The Agency goes to great lengths to ensure that the highest level of expertise and the greatest level of impartiality are achieved in the assignment of panel members and consultants to various product reviews. Sometimes the Agency determines that a potential participant has a real or apparent conflict requiring exclusion from participation in the meeting. At other times, the Agency grants a waiver for participation in the meeting if the size of the potential participant's interest is not so substantial as to be likely to affect the integrity of the services to be performed.

These procedures were followed in the case of this panel meeting, and there was no participating panel member who had a prohibitive conflict of interest concerning this PMA. In fact, I understand that two of the three panel members granted waivers for this meeting voted for your PMA as approvable with conditions.

You stated that the panel did not follow CDRH's procedures when the panel statistician made a motion to approve the product with conditions. It is unclear to me whether this attempt by the panel member to add conditions to the proposed motion (approvable with conditions) was inappropriately blocked. In order to ensure that the Agency was aware of any conditions the maker of the motion might have intended at the December 10 panel meeting, ODE asked her immediately after the meeting to send the Agency any additional recommendations she had with respect to her original review and to topics discussed at the panel meeting. She did so, ODE sent you a copy of her recommendations on January 10, and her comments were incorporated into our final review deliberations. Although we certainly recognize that there were multiple opinions expressed and conclusions reached by different members of the panel, we believe the votes represented the majority view that additional clinical data was required in order to place the submission in approvable form. As part of our continuing efforts to enhance the panel process, ODE has re-trained all panel Executive Secretaries in procedures for handling proposed motions.

You also expressed concerns regarding interactions with the Agency following the panel meeting. Those concerns included what you perceived as the Agency's unwillingness to engage in substantive discussions to address the panel concerns, your receipt of a faxed not approvable letter less than 24 hours prior to your meeting with ODE on January 24, 2003, and your conclusion that the letter negated the utility of the meeting.

I can understand and appreciate your frustration with this part of the process. In an effort to help you understand why events occurred when they did and the Agency's motivations, I will outline the ensuing events as I understand them.

It was clear, shortly after the December 10 Panel meeting, that your firm wished to meet with ODE as soon as possible so that: (1) you could find out what ODE would require of you for PMA approval; and (2) you could discuss a proposal for a post-approval study. In response, ODE told you that no substantive guidance could be provided until the review staff had had a chance to study the notes and transcript from the panel meeting, to review the memorandum from the panel statistician, and to confer with each other and with ODE management. Given those constraints and the approach of the holidays, ODE informed you that the earliest meeting date would be January 13, 2003. As it turned out, ODE had not finished its review of those materials and its deliberations by that time, so we rescheduled the meeting for January 24.

The Center completed its internal deliberations and finalized the decision letter on January 22. During telephone discussions between division staff and a representative of CTI, we informed your representative that a letter was in the final stages of development. Your representative called us repeatedly on January 23 to request the letter, we presumed as a way of preparing for the meeting. We faxed the letter to the hotel fax number your representative provided us because we believed that the company recognized that the letter, which states the scientific basis for our decision, would serve as a concrete framework for discussing next steps. We anticipated that the discussion on January 24 would focus on those next steps and what could be done in order to bring the PMA into approvable form.

Your recent letter of March 6 reiterates a number of the concerns you previously raised and which I have addressed earlier in this response. Your latest letter also provides summary data from an additional fourteen patients as further evidence that additional studies are not necessary to ensure the safety and effectiveness of your device prior to marketing. The Agency does not find this type of information persuasive in recommending a change in the way millions of women at risk for breast cancer are clinically managed.

We understand that you are disappointed in the Agency's not approvable decision, and that you disagree with the scientific basis for the decision. We understand also that you believe the Agency's not approvable decision might have been different if the review process had gone more smoothly. We disagree, but recognize that you may wish to seek redress on the scientific and/or the procedural issues. The CDRH Ombudsman is working with you to identify potential routes of appeal.

We remain committed to working with you as you consider further study of your device.

Sincerely,

Linda S. Kahan

Linda S. Kahan
Deputy Director
Center for Devices and
Radiological Health