Exhibit 23

SIDLEY AUSTIN BROWN & WOOD LLP

BEIJING
BRUSSELS
CHICAGO
DALLAS
GENEVA
HONG KONG
LONDON

1501 K STREET, N.W.
WASHINGTON, D.C. 20005
TELEPHONE 202 736 8000
FACSIMILE 202 736 8711
www.sidley.com

FOUNDED 1866

LOS ANGELES
NEW YORK
SAN FRANCISCO
SHANGHAI
SINGAPORE
TOKYO
WASHINGTON, D.C.

WRITER'S DIRECT NUMBER
(202) 736-8069

WRITER'S E-MAIL ADDRESS
tcgreen@sidley.com

May 13, 2004

By Email and Federal Express

Dr. Crawford
Acting Commissioner
Food and Drug Administration
HF1
14-71 Parklawn Building
560 Fishers Lane
Rockville, MD 20857

Re: Computerized Thermal Imaging, Inc. – PMA Claim

Dear Dr. Crawford:

I represent Computerized Thermal Imaging, Inc. (CTI). I am writing to you to request that further consideration be given by your office to approving CTI's PMA claim. The accumulated agency history with respect to this matter is troubling and reflects a very flawed process which is manifestly unfair.

In particular I draw your attention to the following prior correspondence. (A) Email letter to Dr. Crawford from Dr. Parisky, dated March 18, 2004; (B) Email to General Secord from Dr. Schultz dated March 19, 2004 and (C) letter to General Secord and Jack Martin from Dr. Lumpkin dated March 6, 2004, but not delivered until thirty days later. Copies of this correspondence are enclosed with this letter.

CTI has had to contend with unjustified FDA red tape for years, but it has always attempted to work with the agency in good faith. The inexplicable actions of the FDA with respect to CTI over the past two years have been ruinous and have unlawfully disadvantaged CTI. Many examples of irregularity and inconsistent treatment by the FDA can be cited with respect to this matter, to include FDA's assessment of statistics; its handling of conflicts of interest and its backtracking through approvals/acceptances and reversals.

The second and third referenced messages are but the latest examples of the FDA's unwillingness to consider this matter free from bias and capricious analysis. There is no way to reconcile the communications received from the agency, and a review of the record demonstrates what is obvious: that FDA is determined to disapprove CTI's BCS 2100 system at any cost and without regard to its regulatory mandate.

The Ref B. message purports to represent 3 alternative (new) ways to PMA for the CTI BCS 2100. In fact, alternative #1 is not new except that ODE (Office of Device Evaluation) raises the bar much higher by requiring a clinical study of 3750 patients. The FDA staff approved without qualification a far lower number of patients (490) two years ago.

It is critical to recall that FDA convened their Advisory Panel meeting based on ODE's satisfaction with the CTI numbers – this decision was taken in July 2002. The sudden, unwarranted increase in study size is arbitrary and undertaken for no reason other than to prevent the use of CTI's device at the eleventh hour. The rationale for this new requirement is illogical, and it stands in sharp contract to Dr. Lumpkins' assurance to us that all outstanding points of disagreement between the Agency and CTI had been resolved in CTI's favor save the implications of the one "missed malignancy" in the CTI analysis.

The Ref A letter from Dr. Parisky is clearly dispostive of the "missed malignancy" issue. Dr. Parisky's description of the one "missed" case is absolutely compelling and puts the safety issue to rest. ODE's inexplicable stance translates to a finding that 99.05% (correct on 104 of 105 cases) is not good enough for FDA. This profound degree of caution might be remotely defensible if a physician were not in the diagnostic loop – but this is not the case. Instead, Dr. Schultz suggests through fuzzy logic the use of "lower confidence bonds for NPV" which were not even considered for the analysis until many years after FDA accepted the CTI protocol, 5 modules of submissions, countless meetings, 7 years of effort, a confirmatory study, an Advisory Panel and over $50 million of public shareholders' funds. Moreover, the notion of NPV was dismissed by FDA in a meeting on March 21, 1997 between Dr. Schultz, Dr. Sacks and Mr. Jack Monahan and 3 CTI representatives. All of this is documented. The next time NPV was mentioned by FDA was in a meeting on April 15, 2003 (5 months after the Advisory Panel) which amounted to nothing more than a transparent attempt to withhold PMA. Any objective observer to this process would quickly understand that CTI was caught in a shell game.

CTI has now received a letter from Dr. Lumpkin (Ref C) dated March 6, 2004, which the agency claims was delayed in transmittal for 30 days. The letter goes through a statistical excursion dealing with "sensitivity" not Dr. Schultz's NPV, which is an entirely different concept. Moreover, this letter improperly penalizes CTI stats for "the small number of patients in this valuable group". For the record, this "small number" was approved by FDA without reservation almost 2 years ago. Remarkably, in Ref. C Dr. Lumpkin also suggests CTI consider a 510(k) marketing clearance, an approach the same Dr. Schultz specifically disapproved by letter on May 1, 2003.

Valuable

Janice
301-827-2410
corrected

The other two alternatives listed in Ref. B would require an entirely new concept for clinical trials. CTI will study these two suggestions when and if funds become available.

CTI's years' long campaign to obtain FDA PMA for the BCS 2100 is a story of unfair and inconsistent treatment on the part of FDA. It is unconscionable for the FDA to claim so late in the day that CTI must be statistically penalized for a data set which is too small – said data set having been previously approved as adequate. This turnaround, added to all the other fouls incident to the run-up to the Advisory Panel in December 2002 (*i.e.*, Dr. Sacks' poison pen letter to panelists in October 2002 – later reversed; the sneak attack return to ROC analysis during the Panel hearing after ROC analysis was discarded by FDA in April, 2002; the inclusion at the eleventh hour of three panelists with declared potential financial conflicts of interest for which CTI was permitted no remedy) makes this whole story a sorry travesty.

And, to illustrate further how senseless this process has been, FDA now knows that the BCS 2100 has been licensed without restrictions for use by Health Canada, and ODE knows as well that the CTI machine outperforms all other adjunctive modalities. Against this entire background it is hard to escape the conclusion that forces are at work to favor and protect the mammographic xray industry, to the detriment of a large segment of our population. This perversion of the regulatory process has been directly responsible for the near destruction of CTI, enormous losses to its many thousands of public investors and the withholding of this valuable diagnostic tool from the fight against breast cancer.

It should be understandable why the Company is exhausted, frustrated and upset. Given Dr. Parisky's detailed explication and justification regarding the single "missed case" (Ref. A), CTI requests that PMA be granted immediately for the benefit of American women. This is the only just course of action. Moreover, approval will prevent further escalation of this controversy, which is inevitable if this matter continues unresolved.

Sincerely yours,

Thomas C. Green

TCG:st

Enclosures

cc: Dr. Lumpkin
Senator Orrin G. Hatch
Senator Gordon H. Smith
Congresswoman Darlene Hooley
Congressman Rob Bishop
Tommy G. Thompson, Secretary;
U.S. Dept. of Health & Human Services

From: yuri parisky [mailto:yparisky@usc.edu]
Sent: Thursday, March 18, 2004 8:56 AM
To: d.commissioner@fda.gov
Subject: CTI

Dear Dr. Crawford:

I have been asked to write you an email regarding the Thermal Imaging work I have done for Computerized Thermal Imaging. I am an Assoc. Professor of Radiology at USC School of Medicine. I am the Chief Mammographer and Director of Breast Imaging at the USC/Norris Comprehensive Cancer Center, and NCI designated facility.I was the principal investigator for the multi center trial sponsored by CTI. I am the lead author of the scientific paper discussing the trial which appeared in the American Journal of Roentgenology.

I am familiar with the case in which a mass, eventually demonstrated as a malignancy on biopsy did not register above the threshold for biopsy in the CTI trial. Previously I have discussed this case in my testimony at the FDA panel hearing.

This case is interesting from many aspects. A woman in her 40's, with a family history of Breast Cancer was noted to have a 1 cm mass on mammography. The lesion was spiculated, raising a concern for malignancy. It was deemed a BIRAD4 . The lesion underwent evaluation by the CTI technology, and 3 blinded independent physicians obtained near identical readings of 18.0-18.8, just beneath the threshold of 20.59 for biopsy recommendation. The lesion was evaluated by ultrasound as a hypoechoic mass and subsequently biopsied.

The lesion, on pathology, was a solid ductal carcinoma in situ. DCIS, a pre-invasive cancer usually presents as calcifications on mammography. It has not invaded the basement membrane, and as an in situ lesion, does not have propensity to spread to lymph nodes or metastasize. It may develop eventually into an invasive breast cancer, but at time of diagnosis was a curable, non invasive lesion. Interestingly, DCIS rarely presents as a solid non calcified

lesion, on the order of 5%.

The lesion would have undergone biopsy based on conventional imaging standards. A new mass with both mammography and ultrasonographic suspect

characteristics. A "negative" CTI reading would not have deterred a biopsy, as
the information obtained is not interpreted in a vacuum, but in conjunction
with all imaging tests. An adjunctive procedure.

>From a medical standpoint, this case raises and demonstrates some very provocative issues.

First, the CTI study did not "miss" a single invasive cancer amongst the

masses. No woman would have been harmed by adhering to the results generated
by the CTI study. The below threshold reading for the DCIS is not unusual.
Contrast MRI of the breast, the "gold standard" for adjunctive breast imaging
fails to detect DCIS at least 20-30% of the time. DCIS, in varying grades, may
not influence it's environment enough to promote angiogenesis, or other factors, which is the physiological platform for the detection with MRI,
and
likely the CTI technology.

The technology CTI proposes would assist radiologists in evaluating masses in
an adjunctive manner, and confirming a likely benign assessment to the multitude of benign lesions such as fibroadenoma, fibrosis, etc which would
obviate the need for biopsy in hundreds of thousands of women annually. And,
in our trial, no invasive cancer presenting as a mass fell below our biopsy
recommendation threshold.

Please feel free to seek further inquiry if necessary.

Yuri Parisky, MD
Director of Breast Imaging Services
USC/Norris Cancer Center

RV Secord

From: Schultz, Daniel [DBS@CDRH.FDA.GOV]
Sent: Friday, March 19, 2004 5:23 PM
To: 'rvsecord@gnt.net'
Cc: Feigal Jr., David W; Crawford, Lester, D.V.M.; Lumpkin, Murray; Phillips, Robert A (CDRH); Brogdon, Nancy C.
Subject: CTI study suggestions

General Secord,

I am sending you this memo as follow-up to discussions between yourself and the commissioner's office regarding potential next steps for the CTI marketing application. Our goal is to outline approaches which have been successful with other applications for devices with similar indications.

If you have questions or need additional clarifications please feel free to contact the division and/or myself.
<<CTI options memo>>

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Administration

Food and Drug

Memorandum

Date: March 19, 2004

From: Chief, RADB/DRARD/ODE/CDRH

To: Director, ODE/DRARD
Through: Director DRARD/ODE /signed/Nancy C. Brogdon

Subject: Potential bases for premarket approval of Computerized Thermal Imaging, Inc. (CTI) diagnostic breast device.

A. The approach used in P010035.

The sponsor's proposed indications for use for the CTI devices were as follows:

> The CTI BCS 2100 is a dynamic computerized infrared (IR) based image acquisition and analysis system intended for use as an adjunct to mammography to safely avoid biopsy of benign breast masses that would otherwise have undergone biopsy. A physician should not base a decision for patient care solely on the results of testing with this device, but rather on the results of this test in combination with all other findings and risk factors associated with a specific patient. The CTI BCS 2100 provides additional information to guide a breast biopsy recommendation.

The present device is indicated for and was studied for reducing the number of biopsies performed on women with suspicious findings on mammography. The device focused on those women who had a BIRADS 4 score (BIRADS 4 means that there is a suspicious lesion and biopsy is suggested). If the CTI device indicates that cancer is not present, the patient's score is reduced to BIRADS 3 (BIRADS 3 means that the lesion is probably benign; short term, 6 month follow-up is recommended). The problem with this approach is that it does not account for CTI device false-negatives or how many cancers can be missed in achieving a reduction in the biopsy rate for women who do not have cancer.

To address this problem we need to refer to the existing mammographic practice. Currently approximately 2% of the population of BIRADS 3 patients will be found on follow-up to have cancer. This rate is accepted in current practice. To remain consistent with this, the CTI device would need to show a negative predictive value (NPV) of 98%. In other words, CDRH would find the device, with the current indication, acceptable if a study showed the lower confidence bound of the negative predictive value (NPV) to be 98%, which would be equivalent to the generally accepted criterion for the BIRADS 3 category (short-term follow-up) of mammography. We estimate that about 3750 patients would need to be studied to accomplish this, assuming that the point estimate for NPV found in the PMA study holds.

B. Other acceptable approaches

CDRH has approved two other devices with similar indications, but on different target populations from that intended by CTI. These are the TransScan "T-Scan 2000" and the ATL Ultramark HDI Ultrasound System.

1. TransScan "T-Scan 2000" P970033

The indications for use for this device are as follows:

> The T-Scan 2000 is intended for use as an adjunct to mammography in patients who have equivocal mammographic findings within ACR BIRADS categories 3 or 4. In particular, it is not intended for use in cases with clear mammographic or non-mammographic indications for biopsy. This device provides the radiologist with additional information to guide a biopsy recommendation.

This device is intended to look at both BIRADS 3 and 4 patients. In use it will find BIRADS 4 patients for whom it indicates that biopsy is not warranted and who should be lowered to BIRADS 3. This group will contain some false negatives. However, the device will also find some patients with cancer who should be raised from BIRADS 3 to BIRADS 4 and thus undergo immediate biopsy. FDA's criterion for approval of the device was that, if the study results were extrapolated to a typical U.S. screening population, it would have found more BIRADS 3 patients with cancers than BIRADS 4 patients who were false-negative. Thus, there would be a net gain in the number of detected cancers.

If CTI followed this model and had a successful study, it could change its indications for use to the following:

> The CTI BCS 2100 is a dynamic computerized infrared-based image acquisition device intended for use as an adjunct to mammography in patients with breast lesions *[or masses]* of intermediate suspicion (BIRADS 3 or low-4) that are being considered either for short-term follow-up or immediate biopsy. It is not intended for use in lesions with clear indications for biopsy (BIRADS high-4 or 5). The CTI BCS 2100 provides additional information to guide a breast biopsy recommendation.

This indication for use would have the effect of offsetting missed cancers with newly discovered cancers that had been missed by mammography. Because for CTI this would be a new indication for use, a new clinical study would be needed. However, the number of subjects would be considerably less than 3750 (the number of patients needed to support the previously requested indication for use). We would accept as sufficient a study that showed that the overall increase in cancers found was statistically significant.

2. ATL Ultramark HDI Ultrasound System P940005

The indications for use for this device are as follows:

> The ATL Ultramark™ 9 High Definition Imaging (HDI™) Ultrasound System with L10-5 Scanhead is indicated as an adjunct to mammography and physical breast examination, to provide a high degree of physician confidence in differentiating benign from malignant or suspicious breast lesions. This device provides the physician with additional information to guide a biopsy decision.

Utility of this system has been demonstrated for lesions with an indeterminate Level of Suspicion (LOS 2-4) by conventional diagnostic modalities. Using the HDI system in the evaluation of solid mass characteristics can reduce the number of biopsies performed on indeterminate lesions.

A multi-site study was conducted to investigate the clinical utility of the ATL HDI for the differentiation of benign and malignant breast lesions when used adjunctively to mammography and physical examination. The study compared the HDI ultrasound results, both with and without Doppler, to the radiologic results of suspect lesions with the gold standard of pathology results from biopsy. Each of the subjects enrolled in the study had a previous suspicious finding resulting in a biopsy recommendation. Observations consisted of gathering HDI data from subjects per the protocol. Blinded investigators scored the level of suspicion (LOS) three times for each subject: a) pre-HDI on the basis of mammography (scored again for those subjects by the blinded investigators, that resulted in different levels of suspicion from those that led to their original biopsy recommendations and that spread the levels out over a wider range), b) HDI 2D grey scale, and c) HDI grey scale plus Doppler results. A final diagnostic determination that a mass was likely malignant or benign was also made by the investigator. This information was then compared to the pathology reports and ROC analysis, using level of suspicion as the variable threshold, and performance parameters results were calculated.

Approval by CDRH was based on the fact that the HDI Ultrasound System, when used adjunctively with mammography and physical exam, would significantly reduce the biopsy rate, without any increase in false negatives, when used on masses classified by mammography and physical exam as intermediate (LOS 2, 3, or 4). If the HDI results were used to determine the need for biopsy in the study, 40.1% of a total of 431 patients, with 431 masses of intermediate suspicion, but benign, would not have received a biopsy. The ROC curve of the HDI-Doppler results proved to be statistically significantly higher than that of mammography and physical exam when specifically evaluating the indeterminate study group.

CTI could consider following this model for study design and indications for use.

In conclusion, the use of either the TransScan approach of a trade-off between cancers and non-cancers in BIRADS 3 and 4 or the ATL approach of ROC analysis of adjunctive use on intermediate suspicion women (LOS 2, 3, or 4–which is roughly equivalent to the target population for the TransScan device, i.e., BIRADS 3 and 4) might also lead to approval of CTI's BCS 2100. A new clinical study would be needed, but with considerably fewer than the 3750 subjects that CTI's previous target population would require.

06 April 2004

COVER NOTE TO:

General Richard V. Secord
Mr. Jack W. Martin

Dear General Secord and Mr. Martin,

When I returned yesterday from my holiday, I discovered that the attached letter that I had written prior to leaving on my holiday and that went through the clearance process here in early March was unfortunately never mailed. I understand that there has been subsequent communication between CDRH and you during March; however, I did want to send you the letter to document the status of our discussions as of the end of February.

I do apologize for the delay in its issuance.

Sincerely,

Murray M. Lumpkin, M.D.
Principal Associate Commissioner

FROM :LUMPKIN FAX NO. :3018274001 Apr. 06 2004 12:45PM P3

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

06 March 2004

Richard V. Secord
Major General, USAF (Ret)
Chief Executive Officer - Chairman of the Board
Computerized Thermal Imaging, Inc.
1719 West 2800 South
Suite 102
Ogden, Utah 84401

Dear General Secord:

On 12 December 2003, I wrote you a letter in response to a 29 July 2003 letter from John Brenna (President, Computerized Thermal Imaging) to Dan Troy, (Chief Counsel, Food and Drug Administration). My letter to you stated that FDA believes that the data in your PMA are inadequate to support the safety and effectiveness of the device for the indication you sought in the PMA. To establish that the device is safe and effective for this "delay in biopsy" intended use, the scientific evidence would need to address the significant risk of harm stemming from a delay in the diagnosis of a woman's breast cancer.

After receiving the letter, you requested the opportunity to meet with me to explain why you believed that the data in your PMA did support such an indication and why the FDA has erred in reaching the decision not to approve the application. Dr. Robert O'Neill (Director of the Office of Biostatistics in FDA's Center for Drug Evaluation and Research) and I met with you and your advisers in January and had an in-depth discussion of your perspectives on the scientific data in your PMA and its statistical interpretation.

In order to provide the most comprehensive assessment of your perspectives on the data in the PMA that I could, I undertook a personal, primary review of the clinical components of the PMA itself. Dr. O'Neill provided me statistical consultation. On 23 February 2004, Dr. O'Neill and I presented our evaluation of the clinical section of the PMA to Drs. McClellan and Crawford, and I offered them a series of options based on the scientific data in the PMA.

After this presentation and discussion, Dr. McClellan decided that the Center for Devices and Radiological Health (CDRH) had not erred in its decision regarding the evidence provided by the data in the PMA and the evaluation of benefit and risk, and that the decision was consistent with FDA's public health mission. He decided that CDRH had correctly determined that you had not provided adequate data supporting the reasonable assurance of safety and effectiveness of the device. The evidence presented did not adequately

address the risk that use of the device could unduly and unintentionally delay the diagnosis of a woman's breast cancer in a significant number of patients. Specifically, in the "masses" subset analysis, the data indicated that the device would prevent around 20% of the biopsies of "masses" that ultimately were found to be benign. However, even though the point estimate of the ability of your device to correctly predict which "masses" would be malignant was 99%, because of the small number of patients in this evaluable group, the lower bound of the 95% confidence interval around this point estimate, (including a liberal Bonferoni correction for the subset analysis), is approximately 93%.

As you know, this means that, based on your present data in this subset, your device could result, worst case, in the delay in diagnosis of up to 7% of patients with breast malignancies who otherwise would have been biopsied. If one considers that approximately 20% of the 1,000,000 women who receive breast biopsies in the United States annually have lesions that are malignant, the present data for your device would predict that, were it to be used in all these lesion evaluations, in the worst case approximately 14,000 women would have delayed diagnosis of their breast cancer. This would present an unreasonable risk, and it cannot be determined, based on the evidence presented, that the probable benefits to health from use of the device for its intended uses and conditions of use, even when accompanied by directions and warnings against unsafe use, outweigh any probable risks. Accordingly, the Commissioner determined that CDRH correctly found that your application evidenced a lack of a showing of reasonable assurance that the device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling, and a lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling. Therefore, the PMA for your device cannot be approved at this time for the conditions of use in the proposed labeling.

All of this was discussed with you during the telephone conversation Dr. Lester Crawford and I had on 27 February 2004 with you, Mr. Brenna, and Mr. Martin.

Possible "next step" alternatives that were discussed during that conversation included:

(a) If you wished to continue to pursue the "delay in biopsy" indication, it was suggested that you consider conducting a new study prospectively focused on the population that your present data appears to predict will have the best chance of benefit (decrease in biopsies of benign lesions) with the least chance of risk (delayed biopsies of malignant lesions). That population appears to be women with what are defined in your present protocol as having "masses" (as opposed to "microcalcifications" or "distortions"). Based on the experience with the malignancy that was "missed" with your present interpretive criterion of 20.59, you may want to consider revising your interpretive

criterion to increase your device malignancy detection sensitivity. Although this would result in a corresponding decrease in your device specificity with regard to predicting benign lesions, one would predict from your present data that there should still be a clinically and statistically significant decrease in the number of biopsies of benign lesions. If you were to pursue this option, CDRH will designate prior to the conduct of a new study, an acceptable lower bound of the 95% confidence interval around the point estimate of the sensitivity of the device to accurately detect malignant lesions that would be necessary for a PMA for your device to be approved for this indication in this population. This should allow you to estimate prospectively the numbers of patients such a study would need to enroll to meet the pre-specified criteria.

(b) You might want to consider studying the device in a population of patients for whom the physician believes the decision on biopsy (based on family history, medical examination, and mammography) is still equivocal. In this scenario, the question being tested in a clinical trial would be whether or not your device was able to help with that decision such that more of the malignant lesions would have proceeded to biopsy and fewer of the benign lesions would have proceeded to biopsy.

(c) You made a suggestion regarding an imaging / biopsy-guiding claim in women with BIRAD 4 and 5 lesions who are going to biopsy. As I understood your proposal, this would not be a claim to delay biopsy, but rather would be a claim of adjunctive utility in the guidance of a biopsy. Whether or not you have data to support such a claim was something you and your advisers were going to investigate and inform us of any alternative such indication you thought your present data might support. Should you decide to pursue such a new claim using your present data, CDRH stands ready to work with you on that submission.

One final alternative suggestion for your consideration remains the previous suggestion that a 510(k) marketing clearance may be possible for another indication for use, under a notification identifying other thermal imaging devices as predicate devices. I understand that such market entrance is not what you had originally hoped. Whether or not it is a viable market entrance from your corporate perspective, we would not know here at FDA. I only offer it here for your consideration for completeness. Again, should you wish to pursue this avenue further, CDRH stands ready to work with you on a 510(k) notification for another indication for use.

Please do not hesitate to contact me if I can provide any further information or be of further assistance.

Yours sincerely,

Murray M. Lumpkin

Murray M. Lumpkin, M.D.
Principal Associate Commissioner