

Exhibit 7

From: Monahan, John C. [JCM@CDRH.FDA.GOV]  
Sent: Monday, May 13, 2002 11:15 AM  
To: 'lynns@cti-net.com'  
Subject: RE: CTI Proposal

Lynnn,

I have conferred with Harry Bushar, Bill Sacks, and Bob Phillips. Everyone has looked over the proposal you send to us and is fine with it. You can initiate analyzing the data for the confirmatory study. I look forward to receiving your next submission.

Best regards,

Jack

-----Original Message-----

From: Lynn Satterthwaite [mailto:lynns@cti-net.com]  
Sent: Saturday, May 04, 2002 11:59 PM  
To: John C. Monahan (E-mail)  
Subject: CTI Proposal

Jack,

Per my phone discussion with you on Wednesday, CTI held a conference call Thursday morning with Dr. Bushar and Dr. Sacks. During this call, we (CTI) proposed analyzing an existing set of patients to provide a confirmatory study in response to your letter dated 10 April 2002. We are prepared to proceed with unblinding and analysis of these subjects at this time; however, Dr. Sacks requested that we prepare this proposal and synopsis of our morning's discussion for review by FDA personnel before unvaulting. CTI management is more than anxious for me to move this along, so your timely review and feedback are appreciated. The key points of the discussion, including details about our approach, are included below.

1. We will use a set of patients enrolled in the previous clinical trial. We are still blinded to the pathology of these patients, and have not, therefore, analyzed their efficacy data. They were included, however, in overall subject accountability, safety and demographic reports in Module 5.
2. Drs. Sacks and Bushar agreed that analysis of these data will be considered a prospective study, as our hypothesis will be declared in our analysis plan prior to becoming unblinded to pathology results.
3. The patient set includes 275 patients from three sites. There were 80 lesions described as masses. These patients were enrolled under the same protocol as the patients reported in Amendment 4. We have not performed the analysis for these patients and Quintiles holds the pathology results.
4. We anticipate showing device efficacy comparable to previous results in a group of patients presenting with masses which are going to biopsy in the absence of additional diagnostic information such as that provided by the CTI BCS 2100 device. Previous results indicated that the device operates at high

sensitivity for patients with masses, and increases specificity relative to the biopsy recommendation which is assumed to have a specificity of zero.

5. We will also analyze the relationships of IOS to benign mass size and to surrounding breast density and confirm consistent trends. Upon reflection and review, we agree that our attempt to determine depth via mammography films may not yield accurate results. Since this patient set was enrolled under the same protocol as the patients we reported in Amendment 4, we will not have better depth information for this group of data and, therefore, will not attempt to confirm that depth of the mass within the breast does not affect the device Se/Sp.

6. We discussed the numbers in the proposed study and estimated that we would have between 15% and 20% malignant masses. When the malignant masses in the confirmatory set are added to those in the main study, we would have over 100 malignants which, if all new malignant masses are correctly evaluated, will result in a lower confidence bound for sensitivity of 97%. Dr. Sacks indicated that 97% would be good, citing his own notes that BIRADs 4s and 5s together are about 80% sensitive.

7. We discussed the probability that, no matter how well the device performs in clinical trials, a malignant mass will eventually be missed in clinical practice. The possibility was discussed that this could be addressed by including in the labeling a recommendation that those patients who get a negative reading by CTI would go into a six-month follow-up, much like a BIRAD 3.

With your agreement to this proposal, we will proceed to unvault the pathology results, analyze performance for these patients, and report our findings in a forthcoming amendment.

Lynn'