

**PANEL DISCUSSION QUESTIONS**  
**Computerized Thermal Imaging, Inc.**  
**Breast Cancer System, BCS 2100--P010035**  
**Radiological Devices Advisory Panel**  
**December 10, 2002**

**1. Clinical data**

a) The data in Amendment 4 were selected retrospectively from the original PMA dataset, albeit based on lesion type analyses that were prospectively planned for in the clinical trial protocol. Are the data from Amendment 4 applicable for the assessment and determination of effectiveness of the BCS 2100?

b) The additional data in Amendment 5 consist of 78 masses. Are these additional data by themselves sufficient for the assessment and determination of effectiveness of the BCS 2100?

c) When combined, Amendment 4 provides 84% (412) of the masses and Amendment 5 provides 16% (78). What is the validity of combining these data to assess and determine effectiveness of the BCS 2100?

**2. Please discuss the same questions for safety.**

**3. Please discuss whether safety and effectiveness has been established. As part of this, please discuss the risk/benefit trade-off whereby a false negative results in a 6-month delay of cancer diagnosis and a true negative obviates biopsies that would otherwise turn out benign.**

**4. Is the proposed labeling adequate to ensure safe and effective use of the BCS 2100? Please include in your discussion the following specific items:**

a) Given that only 2 of 105 cancers were smaller than 5 mm, should the labeling specify a lower size limit for an eligible mammographic mass? If so, what size limit?

b) Should the labeling address lesion depth? If so, in what way?

**5. Should the labeling be revised to address any potential psychological impact of a positive mammogram, followed by a positive BCS 2100 result, on a woman who does not, in fact, have cancer (i.e., false positive)?**

**6. Do the above, or any other, issues**

a) require resolution before approval of the PMA?

b) suggest the need for a post-market study?

