



March 25, 2003

Mark B. McClellan, M.D.
Commissioner of Food and Drugs
5600 Fishers Lane Room 1471
Rockville, Md. 20857

Subject: Computerized Thermal Imaging – Pre market Approval Application

Dear Dr. McClellan:

On January 27, 2003 and March 6, 2003, I wrote to you regarding the Center for Devices and Radiological Health's Office of Device Evaluation's mishandling of Computerized Thermal Imaging's PMA submission. Although some of the issues have been referenced in brief conversations with members of your staff, I have not received any formal response. Ongoing depletion of company resources combined with the non-approvable PMA status prevents the company from raising capital to continue operations for its important infrared technology research and development. Recently, two developments have come to my attention that again underscore the need for your personal intervention to permit our product to reach the market.

1 – We have just learned that the FDA cleared a 510(k) for Omnicorder Technologies on December 23, 1999 for medical use of an infrared camera. The cleared indication allows an infrared camera system to be used "for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult, pediatric, and neonatal. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting blood perfusion or reperfusion of tissue and organs. This device is intended for use by qualified healthcare personnel trained in its use."

This is trebly significant. First, the 510(k) cites a CTI device - the CTI Bales Thermal Infrared Camera as a predicate device. Second, this 510(k) was cleared at the same time as CTI was discussing its PMA for a very similar indication with ODE. Third, the 510(k) allows adjunctive diagnostic screening of breast cancer with broad use by qualified healthcare personnel, i.e., an intended use that parallels to the proposed PMA claim. The CTI system went through an elaborate and costly PMA submission with controlled and professionally monitored patient studies, demonstrating high sensitivity and specificity performance. The CTI system, as stated many times, would only be marketed to qualified

mammography facilities and under control of a board certified radiologist. The result of all these efforts resulted in a non-approval letter. In contrast, OmniCorder's 510(k) received clearance for a functionally similar claim even though, based on the public summary, there was no clinical data. The disparate handling of these two applications illustrates why we need your assistance. The first module of the CTI PMA was submitted in 1999 and is still not approved; the Omnicorder 510(k), with a similar indication was cleared in three months.

2 – CTI was contacted by the University of Medicine and Dentistry, New Jersey expressing interest in using the CTI breast imaging system for a NIH sponsored project. The goal of the project is to determine the chemical, physical, biological and social factors in the environment that work together with genetic factors that cause breast cancer. UMDNJ is also working with the National Cancer Institute through the Cancer Institute of New Jersey and the Occupational Health Sciences Institute in this endeavor. The grant proposal involves monitoring young females from adolescence into puberty for a period of seven years. Three sites will perform laboratory tests and breast imaging to document and detect physiological differences over normal physical exam procedures. Mammogram x-ray procedures are not recommended for females in this age group. It is estimated that between 2400 and 3000 patients will be part of this total study. UMDNJ requested that CTI provide its system for use in this important study based on its unique imaging design, the ability to capture frontal and lateral views of each breast and for patient comfort and privacy. However, CTI cannot participate in this clinical study based on the current PMA non-approval status. The inability to participate in government sponsored clinical studies not only thwarts the use of new emerging technology, it hampers this government sponsored research project.

It is now almost four months since CTI appeared before the FDA Advisory panel. Continued diminution of resources combined with the non-approval status and the lack of response to our January 27, 2003 and March 6, 2003 letters prevents the company from raising capital to continue operations. Unless swift progress is made towards obtaining approval, we will have to abandon this project.

CTI has throughout this project been willing to discuss any reasonable conditions of approval, such as data analysis, physician training, and post market studies. ODE, though, has refused to discuss any of these options. In order to permit patient access to this device, CTI remains open to discussing conditions of approval.

I ask that this matter be expedited for resolution.

Sincerely,

John M. Brenna
President and COO

Enclosure

OmniCorder Technologies - 510(k) Clearance Letter dated December 23, 1999