Exhibit 3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 1999

Simona Gallagher
Director, Marketing & Regulatory Affairs
Thermal Medical Imaging, Inc.
1760 South Telegraph Road, Suite 202
Bloomfield Hills, Michigan 48302

Re P990018
TMI Thermal Imaging
Dated: February 17, 1999
Received: March 26, 1999

Dear Ms. Gallagher:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has reviewed your proposed premarket approval application (PMA) Shell for modular review of the TMI Thermal Imaging. FDA agrees with your proposed shell and you may begin submitting modules upon receipt of this letter. We understand that your PMA Shell application will be submitted in support of the safety and effectiveness of TMI Thermal Imaging.

Your device has been assigned the PMA Shell number referenced above. Enclosed is a copy of your proposed Shell with a number assigned to each module. When submitting a module for review, the cover letter should clearly identify the submission as a module and should reference both the PMA Shell number and the module number. All modules should be submitted in triplicate to:

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

If you wish to make a change to your PMA Shell, please contact your division representative for further information.

If you have any questions, please contact John C. Monahan or Robert A. Phillips, Ph.D. at (301) 594-1212.

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PMA Shell for Modular Review
Thermal Medical Imaging, Inc.

Cover Page

1. Module 1: Summary Data and Information May 1999

1. Table of Contents
2. General Information:
   Generic name, Trade name, submitter name & address, contact person, device description
3. Summary of safety and effectiveness
4. Introduction:
   General Information about breast cancer, breast cancer detection, current modalities and the TMI Breast Imaging System. This will include a review of the use of thermography, how it has changed over time and why the present technology is more accurate and reproducible than earlier methods.
5. Indications for Use:
   Definition of the use of the device and the condition for which the device has clinical utility
6. Description of the Disease:
   Summary information on breast cancer including incidence, diagnosis and prognosis
7. Patient Population:
   Summary of the population for which the device has clinical utility and the target population in the clinical study.
8. Alternate Practices and Procedures:
   Summary of current modalities for detecting breast cancer and the frequency of breast biopsies compared to the incidence of positive biopsy results.
9. Device Description:
   Summary of major components of the device (Data Acquisition and Clinical Evaluation Systems) which will include a description of each of the components, principles of operation and properties, and the functioning of these components as a single device as an adjunct to mammography in the detection of breast cancer.
10. Marketing History:
    A brief summary statement of the marketing of the device for the intended use described in the PMA.
11. Bibliography and References

2. Module 2: Device Characteristics July 1999

2.1. Table of Contents
2.2. General Information:
Generic name, Trade name, submitter name & address, contact person, device description
2.3. Summary of safety and effectiveness (updated)
2.4. Name and Intended Use
2.5. Description of Data Acquisition System:
Detailed discussion of the components (patient table, air conditioning unit, air flow control, electrical distribution box, mirrors, infrared camera, other components) of the data acquisition system to include structural and functional properties, principles of operation and use in the clinical setting.
2.6. Description of the Clinical Evaluation System:
Detailed discussion of the components of the clinical evaluation system required to analyze and interpret the clinical data obtained during the data acquisition phase
2.7. Software:
Detailed description of all software in the system including software used in development, and various software components in the data acquisition and data analysis systems.

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3. Module 3: Manufacturing Information September 1999

3.1. Table of Contents
3.2. General Information:
Generic name, Trade name, submitter name & address, contact person, device description
3.3. Organization and Personnel:
Identification of the manufacturers of the components which comprise the data acquisition system and the clinical evaluation system. Identification of the manufacturer responsible for constructing the patient table and incorporating it's components.
3.4. Buildings:
Description of the setting in which the manufacturing will be performed.
3.5. Equipment:
Description of the equipment used in the manufacturing of the device.
3.6. Acceptance and Control of Components:
Description of performance standards or the components f the device and validation procedures to ensure standards are met for the final product.
3.7. Production and Process Controls:
Description of all procedures employed in the manufacture of the components and the final product to document the completion of the product according to all specifications
3.8. Packaging and Labeling Controls:
Description of all procedures employed in the manufacture of the components and the final product to document the completion of packaging labeling according to specifications.
3.9. Holding, Distribution and Installation:
Description of device storage, distribution and installation procedures for device at user site.
3.10. Device Evaluation:
Description of procedures to be followed to ensure device meets structural and functional specifications.
3.11. Record Keeping:
Description of all record keeping and documentation associated with the manufacture, testing and installation of the device.
3.12. Certification:
Description of all government and industry certification and compliance issues for the device.

4. Module 4: Non-Clinical Testing October 1999

4.1. Table of Contents

4.2. General Information:
Generic name, Trade name, submitter name & address, contact person, device description

4.3. Summary of safety and effectiveness (updated)

4.4. Bench Testing:
Description of all non-clinical testing of the structural and functional components of the device. Documentation of the development of all performance standards and calibration procedures. Test results, test evaluation and conclusions made based on the results.

4.5. Bio-compatibility Testing:
Description of all materials used in the manufacture of the device that come in contact with the patient and a discussion of all the bio-compatibility testing performed on these materials. Test results, test evaluation and conclusions based on these results.

4.6. Electrical Safety:
Description of all testing performed on the device to document the device is safe from an electrical standpoint. Reference test as it relates to any voluntary standards such as ISO 601-1.

4.7 Electromagnetic Compatibility:
Description of all testing performed on the device to demonstrate electromagnetic compatibility of the device. Alternately, provide a justification for why such testing is not needed.

4.8. Environmental Assessment:
A statement regarding the impact the device has on the environment. Devices sold will have the waste controlled or the waste expected to enter the environment to be non-toxic as provided for in 21 CFR 25.24(e)(7).

4.9. Reliability and Durability:
Description of all testing performed to document the reliability and durability of the device. Test results, analysis of the data and conclusions reached from the data will be provided.

4.10. Stress and Wear:
Description of all testing performed to document the expected life of the components of the device and the development of trouble shooting methods and maintenance of the device to ensure the device is performing within specifications. Results, analysis and conclusions reached from the data.

5. Module 5: Clinical Study December 1999

.1. Table of Contents

.2. General Information:
Generic name, Trade name, submitter name & address, contact person, device description

.3. Summary of Safety and Effectiveness (Final Version)

.4. Clinical Protocol:
Clinical protocol and amendments will be provided

5. Study Objectives and Clinical Hypothesis:
Presentation of the objectives of the study, clinical hypothesis and clinical endpoints, and how these objectives were achieved.

6. Investigative Clinical Sites and Number of Investigators:
Presentation of the clinical sites and the investigators. The number of patients accrued and study duration at each of the clinical sites will be presented.

7. Patient Population:
Presentation of the patient population utilized in the clinical study. This presentation will include inclusion/exclusion criteria, accountability and demographics.

8. Statistical Methods:
Sample size justification and the use of specific statistical methods to demonstrate that clinical endpoints were achieved.

9. Effectiveness Data:
A presentation of the study results by site and pooled across clinical sites. Statistical analysis of the data to demonstrate the effectiveness of the data will be presented (specificity, sensitivity and ROC). Sub-analyses by mammographic abnormality, size of lesion and other categories will be presented.

10. Safety Data:
A presentation of study results will be presented by site and pooled across clinical sites.

11. Patient Complaints:
A description of all patient complaints received during the conduct of the study

.2. Conclusions:
Discussion of conclusions drawn from the clinical study results which demonstrates the safety, effectiveness and clinical utility of the device.

.3. Labeling:
Labeling will include all proposed printed information used to promote the device as well as information accompanying the device for clinical use. The indication for use will be clearly stated. All device user manuals which will be distributed with the device describing the function of all components. The manual will describe all maintenance, cleaning and trouble-shooting and testing procedures to be followed for appropriate use of the device. All contraindications and warnings will be clearly stated. Instructions on installation of the device will be included. A training manual and the intended training for the user site will be defined; to include physician training processes and evaluation parameters.

4. Other Information Requested by FDA