Thermogram Assessment Services 11/10/16

10903 New Hampshire Avenue
Silver Spring, MD 20903

VIA UNITED PARCEL SERVICE

WARNING LETTER
November 10, 2016

Edward B. Jay
Thermogram Assessment Services
904 Silver Spur Rd. #451
Palos Verdes, CA 90274

RE: FDA Reference Number CMS 505591

Dear Mr. Jay:

The United States Food and Drug Administration (FDA) has learned that your firm, Thermogram Assessment Services (TAS), is marketing the TAS Image Analysis Software, including the Spatial Thermographic Imaging (STI),[1] the Integrated Thermography Systems, and Infrared (IR) Cameras (FLIR Systems, Inc. Model 325 and Model 655) (hereinafter referred to collectively as the "TAS Thermal Imaging System"), in the United States without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

Under section 201(h) of the Act, 21 U.S.C. § 321(h), the TAS Thermal Imaging System is a device because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

FDA has reviewed your firm's websites (http://breastthermography.info/, www.thermeval.com, http://www.breastthermographyevaluation.com/, and www.thermogramassessmentservices.com), your firm's September 1, 2015 letter responding to FDA's July 22, 2015 letter, and your November 8, 2015 email to FDA regarding the marketing of the TAS Thermal Imaging System.

Based on this review, FDA has determined that theTAS Thermal Imaging System is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved premarket approval application (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g) for the device as described and marketed. The TAS Thermal Imaging System is also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because you did not notify the Agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the Agency (see 21 CFR 807.81(b)).

In communications with FDA you seem to argue that your marketing of the TAS Thermal Imaging System is permissible because the device has been cleared by FDA. For example, you stated in your September 1, 2015 letter to FDA that the "equipment, systems, and software offered on [your] web site are brokered products available from FLIR Commercial Systems Inc., and which have been cleared for marketing by the FDA for sale." In your November 8, 2015 email to FDA you make similar arguments, noting that the 510(k) number for the IR cameras is K033967.

Although it is true that these IR cameras have been cleared (for a certain intended use) by FDA, such clearance of a component of the TAS Thermal Imaging System does not permit the marketing of the TAS Thermal Imaging System. Moreover, marketing these IR cameras with a major change or modification in intended use would not fall under their current clearance. These telethermographic cameras, which are class I devices regulated under 21 CFR 884.2980(a) ("Teletheromgraphic system intended for adjunctive diagnostic screening for detection of breast cancer or other uses"), were cleared by FDA (K033967) for the following intended use: "The Flir device is intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of differences in skin surface temperature changes. It can visualize, document temperature patterns and changes."**[2]** Marketing these devices for sole diagnostic screening, for example, by stating that they can be used without any other test in the case of negative findings, would constitute a major change or modification in the intended use of the device (see 21 CFR 807.81(a)(3)(ii)), and would require premarket approval (see 21 CFR 884.2980(b)).

General information on the various device regulatory pathways and preparing the appropriate information for premarket submission is available on the Internet at **http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm)**. FDA will evaluate the information that your firm submits and decide whether your product may be legally marketed.

For your reference, we note that telethermographic systems, which may include signal analysis and display equipment and accessories, that are intended for adjunctive diagnostic screening for detection of breast cancer or other uses have been classified as class I devices under 21 CFR 884.2980(a), and require premarket clearance (510(k)) prior to marketing. Telethermographic systems that are intended for use alone in diagnostic screening for detection of breast cancer or other uses have been classified as class III devices under 21 CFR 884.2980(b), and require approval of a PMA prior to marketing. We also note, however, that even if your firm's device is solely intended for adjunctive screening for detection of breast cancer or other uses, it may not be found substantially equivalent to a legally marketed device (predicate) currently classified under 21 CFR 884.2980(a) if your firm's device has different technological characteristics from the predicate device that raise different questions of safety and effectiveness from the predicate device (e.g., a significant change in the materials, design, energy source, or other features of the device (see section 513(f)(1) of the Act (21 U.S.C. § 360c(f)(1)), section 513(i)(1) of the Act (21 U.S.C. § 360c(i)(1)), and the implementing regulations found at 21 CFR 807.100).

Our office requests that TAS immediately cease activities that result in the misbranding or adulteration of the TAS Thermal Imaging System, such as the commercial distribution of the device for the uses discussed above.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please notify this office in writing within fifteen (15) business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, including an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within thirty business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your firm's response should be sent to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
ATTN: Division of Radiological Health
Office ofIn-Vitro Diagnostics and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm. It is your firm's responsibility to ensure compliance with the applicable laws and regulations administered by FDA.

Please refer to CMS 505591 when replying. If you have any questions about the contents of this letter, please contact: Dr. Robert Ochs at 301-796-6661 or Robert.Ochs@fda.hhs.gov.

Sincerely yours,
/S/
Alberto Gutierrez, Ph.D.
Director
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

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[1] This software is also referred to by other names, including the "Breast Thermography Evaluation Program," "Computerized Breast Thermography (CBT) software program," "proprietary interpretation software", "Spatial Thermographic Imaging", and "artificial intelligence computer program", on the TAS's websites identified in this letter.
[2] See Summary of Safety and Effectiveness, available at **http://www.accessdata.fda.gov/cdrh_docs/pdf3/K033967.pdf (http://www.accessdata.fda.gov/cdrh_docs/pdf3/K033967.pdf)**.

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