All devices sold for medical use in the U.S. must be FDA registered (510)k. The infrared imaging system used by us for medical application is an FDA registered Type II medical device. The physical risk to the patient is obviously very low, as a thermography camera does not expose the patient to harmful energy like radiation, but instead captures the infrared energy emitting from the body. However, the FDA is highly concerned about how thermography is represented to the patient, and rightly so.

Therefore, it is important to be aware that thermography is adjunctive. It is not a standalone diagnostic device. In fact, thermography is not recognized by the FDA as diagnostic for any specific disease with the exception of RSD. Thermography is appropriate as a safe and reliable screening device to detect changes that, if left unattended, could possibly progress into a late stage disease that can then be detected by other types of imaging devices. Thermography is not a standalone device and does not replace any other diagnostic device.

The highest and best use of medical thermography is:
A screening device for the purpose of assisting the health practitioner to care for their patients by promoting health and prevention of disease by using the physiological warning signs made possible by thermography or infrared imaging.
Code of Federal Regulations][Title 21, Volume 8][Revised as of April 1, 2006][CITE: 21CFR884.2980]

page1image17112TITLE 21--FOOD AND DRUGS CHAPTER I--FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBCHAPTER H--MEDICAL DEVICES

PART 884 -- OBSTETRICAL AND GYNECOLOGICAL DEVICES
Subpart C--Obstetrical and Gynecological Monitoring Devices Sec. 884.2980 Telethermographic system.
(a) Telethermographic system intended for adjunctive diagnostic screening for detection of breast cancer or other uses--(1)Identification. A telethermographic system for adjunctive diagnostic screening for detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports,component parts, and accessories.

(2) Classification. Class I (general controls).

(b) Telethermographic system intended for use alone in diagnostic screening for detection of breast cancer or other uses--(1)Identification. A telethermographic system for use as the sole diagnostic screening tool for detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports,component parts, and accessories.

(2) Classification. Class III.

(3) Date PMA or notice of completion of a PDP is required. As of the enactment date of the amendments, May 28, 1976, an approval undersection 515 of the act is required before the device described in paragraph (b)(1) may be commercially distributed. See 884.3.

[53 FR 1566, Jan. 20, 1988, as amended at 55 FR 48440, Nov. 20, 1990;66 FR 46953, Sept. 10, 2001]