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TITLE 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 under section 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]