510(k) Premarket Notification Database

Device Classification Name	System, Thermographic, Liquid Crystal
510(K) Number	K971956
Regulation Number	884.2982
Device Name	CRT2000 THERMOGRAPHIC SYSTEM
Applicant	WERNER EIDAM MEDIZIN-TECHNOLOGIE GMBH 1900 K St. N.W. Washington, DC 20006 1108
Contact	Emalee G Murphy
Classification Product Code	LHM
Date Received	05/27/1997
Decision Date	08/22/1997
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Obstetrics/Gynecology
Review Advisory Committee	Radiology
Statement/Summary/Purged Status	Summary Only
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 5/08/2006

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2005]
[CITE: 21CFR884.2982]

See Related Information

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. 884.2982 Liquid crystal thermographic system.

(a) *A nonelectrically powered or an AC-powered liquid crystal thermographic system intended for adjunctive use in diagnostic screening for detection of breast cancer or other uses*--(1) *Identification.* A nonelectrically powered or an AC-powered liquid crystal thermographic system intended for use as an adjunct to physical palpation or mammography in diagnostic screening for detection of breast cancer or other uses is a nonelectrically powered or an AC-powered device applied to the skin that displays the color patterns of heat sensitive cholesteric liquid crystals that respond to temperature variations of the surface of the body. This generic type of device may include patient and equipment supports, a means to ensure thermal contact between the patient's skin and the liquid crystals, component parts, and accessories.

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

(b) *A nonelectrically powered or an AC-powered liquid crystal thermographic system intended for use alone in diagnostic* screening for detection of breast cancer or other uses--(1) *Identification.* A nonelectrically powered or an AC-powered liquid crystal thermographic system intended for use as the sole diagnostic screening tool for detection of breast cancer or other uses is a nonelectrically powered or an AC-powered device applied to the skin that displays the color patterns of heat sensitive cholesteric liquid crystals that respond to temperature variations of the surface of the body. This generic type of device may include image display and recording equipment, patient and equipment supports, a means to ensure thermal contact between the patient's skin and the liquid crystals, 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 48441, Nov. 20, 1990; 66 FR 46953, Sept. 10, 2001]

Database Updated April 1, 2005