

§ 884.2700

monitoring device by means of pinching skin tissue with a nonreusable clip. This device is used to obtain a fetal electrocardiogram. This generic type of device may include a clip electrode applicator.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any fetal scalp clip electrode and applicator that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a fetal scalp clip electrode and applicator that was in commercial distribution before May 28, 1976. Any other fetal scalp clip electrode and applicator shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 12684-12720, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987; 61 FR 50708, Sept. 27, 1996]

§ 884.2700 Intrauterine pressure monitor and accessories.

(a) *Identification.* An intrauterine pressure monitor is a device designed to detect and measure intrauterine and amniotic fluid pressure with a catheter placed transcervically into the uterine cavity. The device is used to monitor intensity, duration, and frequency of uterine contractions during labor. This generic type of device may include the following accessories: signal analysis and display equipment, patient and equipment supports, and component parts.

(b) *Classification.* Class II (performance standards).

§ 884.2720 External uterine contraction monitor and accessories.

(a) *Identification.* An external uterine contraction monitor (i.e., the tokodynamometer) is a device used to monitor the progress of labor. It measures the duration, frequency, and relative pressure of uterine contractions with a transducer strapped to the maternal abdomen. This generic type of device may include an external pres-

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sure transducer, support straps, and other patient and equipment supports.

(b) *Classification.* Class II (performance standards).

§ 884.2730 Home uterine activity monitor.

(a) *Identification.* A home uterine activity monitor (HUAM) is an electronic system for at home antepartum measurement of uterine contractions, data transmission by telephone to a clinical setting, and for receipt and display of the uterine contraction data at the clinic. The HUAM system comprises a tocotransducer, an at-home recorder, a modem, and a computer and monitor that receive, process, and display data. This device is intended for use in women with a previous preterm delivery to aid in the detection of preterm labor.

(b) *Classification.* Class II (special controls); guidance document (Class II Special Controls Guidance for Home Uterine Activity Monitors).

[66 FR 14076, Mar. 9, 2001]

EFFECTIVE DATE NOTE: At 66 FR 14076, Mar. 9, 2001, § 884.2730 was added to subpart C of part 884, effective Apr. 9, 2001.

§ 884.2740 Perinatal monitoring system and accessories.

(a) *Identification.* A perinatal monitoring system is a device used to show graphically the relationship between maternal labor and the fetal heart rate by means of combining and coordinating uterine contraction and fetal heart monitors with appropriate displays of the well-being of the fetus during pregnancy, labor, and delivery. This generic type of device may include any of the devices subject to §§ 884.2600, 884.2640, 884.2660, 884.2675, 884.2700, and 884.2720. This generic type of device may include the following accessories: Central monitoring system and remote repeaters, signal analysis and display equipment, patient and equipment supports, and component parts.

(b) *Classification.* Class II (performance standards).

§ 884.2900 Fetal stethoscope.

(a) *Identification.* A fetal stethoscope is a device used for listening to fetal heart sounds. It is designed to transmit

the fetal heart sounds not only through sound channels by air conduction, but also through the user's head by tissue conduction into the user's ears. It does not use ultrasonic energy. This device is designed to eliminate noise interference commonly caused by handling conventional stethoscopes.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

§ 884.2960 Obstetric ultrasonic transducer and accessories.

(a) *Identification*. An obstetric ultrasonic transducer is a device used to apply ultrasonic energy to, and to receive ultrasonic energy from, the body in conjunction with an obstetric monitor or imager. The device converts electrical signals into ultrasonic energy, and vice versa, by means of an assembly distinct from an ultrasonic generator. This generic type of device may include the following accessories: coupling gel, preamplifiers, amplifiers, signal conditioners with their power supply, connecting cables, and component parts. This generic type of device does not include devices used to generate the ultrasonic frequency electrical signals for application.

(b) *Classification*. Class II (performance standards).

§ 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.

(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]

§ 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.

(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