

§ 884.2225

diagnosis of fetal status and recommendations for labor management and clinical interventions. This generic type of device may include signal analysis and display equipment, electronic interfaces for other equipment, and power supplies and component parts.

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

(c) *Date PMA or notice of completion of 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 October 3, 2000, for any obstetric data analyzer described in paragraph (a) of this section that was in commercial distribution before May 28, 1976, or that has been found, on or before October 3, 2000, to be substantially equivalent to an obstetric data analyzer described in paragraph (a) of this section that was in commercial distribution before May 28, 1976. Any other obstetric data analyzer described in paragraph (a) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[65 FR 41332, July 5, 2000]

§ 884.2225 Obstetric-gynecologic ultrasonic imager.

(a) *Identification*. An obstetric-gynecologic ultrasonic imager is a device designed to transmit and receive ultrasonic energy into and from a female patient by pulsed echoscopy. This device is used to provide a visual representation of some physiological or artificial structure, or of a fetus, for diagnostic purposes during a limited period of time. This generic type of device may include the following: signal analysis and display equipment, electronic interfaces for other equipment, patient and equipment supports, coupling gel, and component parts. This generic type of device does not include devices used to monitor the changes in some physiological condition over long periods of time.

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

§ 884.2600 Fetal cardiac monitor.

(a) *Identification*. A fetal cardiac monitor is a device used to ascertain fetal heart activity during pregnancy and labor. The device is designed to

21 CFR Ch. I (4–1–11 Edition)

separate fetal heart signals from maternal heart signals by analyzing electrocardiographic signals (electrical potentials generated during contraction and relaxation of heart muscle) obtained from the maternal abdomen with external electrodes. This generic type of device may include an alarm that signals when the heart rate crosses a preset threshold. This generic type of device includes the “fetal cardiometer (with sensors)” and the “fetal electrocardiographic monitor.”

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

§ 884.2620 Fetal electroencephalographic monitor.

(a) *Identification*. A fetal electroencephalographic monitor is a device used to detect, measure, and record in graphic form (by means of one or more electrodes placed transcervically on the fetal scalp during labor) the rhythmically varying electrical skin potentials produced by the fetal brain.

(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 electroencephalographic monitor 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 electroencephalographic monitor in commercial distribution before May 28, 1976. Any other fetal electroencephalographic monitor 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]

§ 884.2640 Fetal phonocardiographic monitor and accessories.

(a) *Identification*. A fetal phonocardiographic monitor is a device designed to detect, measure, and record fetal heart sounds electronically, in graphic form, and noninvasively, to ascertain fetal condition during labor.