§ 884.2225 Obstructive-gynecologic ultrasonic imager.

(a) Identification. An obstructive-gynecologic ultrasonic imager is a device designed to transmitt and receive ultrasonic energy into and from a female patient by 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 separate fetal heart sounds from maternal heart sounds 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 cardiograph (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.

§ 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.