

§ 884.4900

system used to examine the vagina and cervix.

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

§ 884.4900 Obstetric table and accessories.

(a) *Identification.* An obstetric table is a device with adjustable sections designed to support a patient in the various positions required during obstetric and gynecologic procedures. This generic type of device may include the following accessories: patient equipment, support attachments, and cabinets for warming instruments and disposing of wastes.

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

Subpart F—Obstetrical and Gynecological Therapeutic Devices

§ 884.5050 Metreurynter-balloon abortion system.

(a) *Identification.* A metreurynter-balloon abortion system is a device used to induce abortion. The device is inserted into the uterine cavity, inflated, and slowly extracted. The extraction of the balloon from the uterus causes dilation of the cervical os. This generic type of device may include pressure sources and pressure controls.

(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 metreurynter-balloon abortion system 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 metreurynter-balloon abortion system that was in commercial distribution before May 28, 1976. Any other metreurynter-balloon abortion system 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 50709, Sept. 27, 1996]

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§ 884.5070 Vacuum abortion system.

(a) *Identification.* A vacuum abortion system is a device designed to aspirate transcervically the products of conception or menstruation from the uterus by using a cannula connected to a suction source. This device is used for pregnancy termination or menstrual regulation. This type of device may include aspiration cannula, vacuum source, and vacuum controller.

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

§ 884.5100 Obstetric anesthesia set.

(a) *Identification.* An obstetric anesthesia set is an assembly of antiseptic solution, needles, needle guides, syringes, and other accessories, intended for use with an anesthetic drug. This device is used to administer regional blocks (e.g., paracervical, uterosacral, and pudendal) that may be used during labor, delivery, or both.

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

§ 884.5150 Nonpowered breast pump.

(a) *Identification.* A nonpowered breast pump is a manual suction device used to express milk from the breast.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9, if the device is using either a bulb or telescoping mechanism which does not develop more than 250 mm Hg suction, and the device materials that contact breast or breast milk do not produce cytotoxicity, irritation, or sensitization effects.

[45 FR 12684-12720, Feb. 26, 1980, as amended at 61 FR 1124, Jan. 16, 1996; 66 FR 38809, July 25, 2001]

§ 884.5160 Powered breast pump.

(a) *Identification.* A powered breast pump in an electrically powered suction device used to express milk from the breast.

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