§ 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 Metreurenty-balloon abortion system.

(a) Identification. A metreurenty-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 dilatation of the cervical os. This generic type of device may include pressure sources and pressure controls.

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

§ 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.

§ 884.5160 Powered breast pump.

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