(17) A nonmetal vaginal speculum is a nonmetal instrument used to expose the interior of the vagina.

(18) A fiberoptic nonmetal vaginal speculum is a nonmetal instrument, with fiberoptic light, used to expose and illuminate the interior of the vagina.

(b) Classification.

(1) Class II (performance standards).

(2) Class I for the amniotome, uterine curette, cervical dilator (fixed-size bougies), cerclage needle, IUD remover, uterine sound, and gynecological biopsy forceps. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §884.9.


§ 884.4550 Gynecologic surgical laser.

(a) Identification. A gynecologic surgical laser is a continuous wave carbon dioxide laser designed to destroy tissue thermally or to remove tissue by radiant light energy. The device is used only in conjunction with a colposcope as part of a gynecological surgical system. A colposcope is a magnifying lens 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).

§ 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...