(7) A vaginal applicator is an instrument used to insert medication into the vagina.
(8) A vaginal retractor is an instrument used to maintain vaginal exposure by separating the edges of the vagina and holding back the tissue.
(9) A gynecological fibroid hook is an instrument used to exert traction upon a fibroid.
(10) A pelvimeter (external) is an instrument used to measure the external diameters of the pelvis.

(b) Classification. Class I (general controls).

§ 884.4530 Obstetric-gynecologic specialized manual instrument.

(a) Identification. An obstetric-gynecologic specialized manual instrument is one of a group of devices used during obstetric-gynecologic procedures to perform manipulative diagnostic and surgical functions (e.g., dilating, grasping, measuring, and scraping), where structural integrity is the chief criterion of device performance. This type of device consists of the following:

1. An amniotome is an instrument used to rupture the fetal membranes.
2. A circumcision clamp is an instrument used to compress the foreskin of the penis during circumcision of a male infant.
3. An umbilical clamp is an instrument used to compress the umbilical cord.
4. A uterine curette is an instrument used to scrape and remove material from the uterus.
5. A fixed-size cervical dilator is any of a series of bougies of various sizes used to dilate the cervical os by stretching the cervix.
6. A uterine elevator is an instrument inserted into the uterus used to lift and manipulate the uterus.
7. A gynecological surgical forceps is an instrument with two blades and handles used to pull, grasp, or compress during gynecological examination.

(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 Gynecological surgical laser.

(a) Identification. A gynecological 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).

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.


§ 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 in an electrically powered suction device used to express milk from the breast.