§ 884.4550  

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 dilatation 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.

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

§ 884.5200 Hemorrhoid prevention pressure wedge.

(a) Identification. A hemorrhoid prevention pressure wedge provides mechanical support to the perianal region during the labor and delivery process. External mechanical support of the perianal region is intended to help prevent the occurrence of external hemorrhoids associated with vaginal childbirth.

(b) Classification. Class II (special controls). The special controls for this device are:

1. The sale, distribution, and use of this device are restricted to prescription use in accordance with §801.109 of this chapter.

2. The labeling must include specific instructions regarding the proper placement and use of the device.

3. The device must be demonstrated to be biocompatible.

4. Mechanical bench testing of material strength must demonstrate that the device will withstand forces encountered during use.

5. Safety and effectiveness data must demonstrate that the device prevents hemorrhoids in women undergoing spontaneous vaginal delivery, in addition to general controls.

[76 FR 21238, Apr. 15, 2011]

§ 884.5225 Abdominal decompression chamber.

(a) Identification. An abdominal decompression chamber is a hoodlike device used to reduce pressure on the pregnant patient’s abdomen for the relief of abdominal pain during pregnancy or labor.

(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 abdominal decompression chamber 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 an abdominal decompression chamber that was in commercial distribution before May 28, 1976.

Any other abdominal decompression chamber shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.


§ 884.5250 Cervical cap.

(a) Identification. A cervical cap is a flexible cuplike receptacle that fits over the cervix to collect menstrual flow or to aid artificial insemination. This generic type of device is not for contraceptive use.

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

§ 884.5300 Condom.

(a) Identification. A condom is a sheath which completely covers the penis with a closely fitting membrane. The condom is used for contraceptive