§ 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.

[45 FR 12684–12720, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987; 61 FR 50709, Sept. 27, 1996]

§ 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 and for prophylactic purposes (preventing transmission of sexually transmitted infections). The device may also be used to collect semen to aid in the diagnosis of infertility.

(b) *Classification.* (1) Class II (special controls) for condoms made of materials other than natural rubber latex, including natural membrane (skin) or synthetic.

(2) Class II (special controls) for natural rubber latex condoms. The guidance document entitled ''Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300'' will serve as the special control. See § 884.1(e) for the availability of this guidance document.

[73 FR 66538, Nov. 10, 2008]

§ 884.5310 Condom with spermicidal lubricant.

(a) *Identification.* A condom with spermicidal lubricant is a sheath which completely covers the penis with a closely fitting membrane with a lubricant that contains a spermicidal agent, nonoxynol–9. This condom is used for contraceptive and prophylactic purposes (preventing transmission of venereal disease).

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

[47 FR 49022, Oct. 29, 1982]