Food and Drug Administration, HHS

§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 II (performance standards).

§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. Class II (performance standards).

§884.5320 Glans sheath.

(a) Identification. A glans sheath device is a sheath which 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 III (premarket approval).

(c) Date premarket approval application (PMA) or notice of completion of a product development protocol (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 September 12, 2002, for any glans sheath that was in commercial distribution before May 28, 1976, or that has, on or before September 12, 2002, been found to be substantially equivalent to a glans sheath that was in commercial distribution before May 28, 1976. Any other glans sheath shall have an approved PMA or declared