§ 884.1175 Endometrial suction curette and accessories.

(a) Identification. An endometrial suction curette is a device used to remove material from the uterus and from the mucosal lining of the uterus by scraping and vacuum suction. This device is used to obtain tissue for biopsy or for menstrual extraction. This generic type of device may include catheters, syringes, and tissue filters or traps.

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

§ 884.1185 Endometrial washer.

(a) Identification. An endometrial washer is a device used to remove materials from the endometrium (the mucosal lining of the uterus) by washing with water or saline solution and then aspirating with negative pressure. This device is used to study endometrial cytology (cells).

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

§ 884.1300 Uterotubal carbon dioxide insufflator and accessories.

(a) Identification. A uterotubal carbon dioxide insufflator and accessories is a device used to test the patency (lack of obstruction) of the fallopian tubes by pressurizing the uterus and fallopian tubes and filling them with carbon dioxide gas.

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

§ 884.1425 Perineometer.

(a) Identification. A perineometer is a device consisting of a fluid-filled sack for intravaginal use that is attached to an external manometer. The devices measure the strength of the perineal muscles by offering resistance to a patient’s voluntary contractions of these muscles and is used to diagnose and to correct, through exercise, urinary incontinence or sexual dysfunction.

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

§ 884.1550 Amniotic fluid sampler (amniocentesis tray).

(a) Identification. The amniotic fluid sampler (amniocentesis tray) is a collection of devices used to aspirate amniotic fluid from the amniotic sac via a transabdominal approach. Components of the amniocentesis tray include a disposable 2 inch 20 gauge needle with stylet and a 30 cc. syringe, as well as the various sample collection accessories, such as vials, specimen containers, medium, drapes, etc. The device is used at 16–18 weeks gestation for antepartum diagnosis of certain congenital abnormalities or anytime after 24 weeks gestation when used to assess fetal maturity.

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

§ 884.1560 Fetal blood sampler.

(a) Identification. A fetal blood sampler is a device used to obtain fetal blood transcrvically through an endoscope by puncturing the fetal skin with a short blade and drawing blood into a
§ 884.1600 Transabdominal amnioscope (fetoscope) and accessories.

(a) Identification. A transabdominal amnioscope is a device designed to permit direct visual examination of the fetus by a telescopic system via abdominal entry. The device is used to ascertain fetal abnormalities, to obtain fetal blood samples, or to obtain fetal tissue. This generic type of device may include the following accessories: trocar and cannula, instruments used through an operating channel or through a separate cannula associated with the amnioscope, light source and cables, and component parts.

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

§ 884.1630 Colposcope.

(a) Identification. A colposcope is a device designed to permit direct viewing of the tissues of the vagina and cervix by a telescopic system located outside the vagina. It is used to diagnose abnormalities and select areas for biopsy. This generic type of device may include a light source, cables, and component parts.

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

§ 884.1640 Culdoscope and accessories.

(a) Identification. A culdoscope is a device designed to permit direct viewing of the organs within the peritoneum by a telescopic system introduced into the pelvic cavity through the posterior vaginal fornix. It is used to perform diagnostic and surgical procedures on the female genital organs. This generic type of device may include trocar and cannula, instruments used through an operating channel, scope preheaters, light source and cables, and component parts.

(b) Classification. (1) Class II (performance standards).

(2) Class I for culdoscope accessories that are not part of a specialized instrument or device delivery system; do not have adapters, connectors, channels, or do not have portals for electrosurgical, laser, or other power sources. Such culdoscope accessory instruments include: lens cleaning brush, biopsy brush, clip applier (without clips), applicator, cannula (without trocar or valves), ligature carrier/needle holder, clamp/hemostat/grasper, curette, instrument guide, ligature passing and knotting instrument, suture needle (without suture), retractor, mechanical (noninflatable), snare, stylet, forceps, dissector, mechanical (noninflatable) scissors, and suction/irrigation probe. 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.


§ 884.1660 Transcervical endoscope (amnioscope) and accessories.

(a) Identification. A transcervical endoscope is a device designed to permit direct viewing of the fetus and amniotic sac by means of an open tube introduced into the uterus through the cervix. The device may be used to visualize the fetus or amniotic fluid and to sample fetal blood or amniotic fluid. This generic type of device may include obturators, instruments used through an operating channel, light