Food and Drug Administration, HHS

§ 884.2050 Obstetric data analyzer.

(a) Identification. An obstetric data analyzer (fetal status data analyzer) is a device used during labor to analyze electronic signal data obtained from fetal and maternal monitors. The obstetric data analyzer provides clinical

do not have adapters, connectors, channels, or do not have portals for electrosurgical, laser, or other power sources. Such hysteroscope accessory instruments include: lens cleaning brush, cannula (without trocar or valves), clamp/hemostat/grasper, curette, instrument guide, forceps, dissector, mechanical (noninflatable), and scissors. 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.


§ 884.1700 Hysteroscopic insufflator.

(a) Identification. A hysteroscopic insufflator is a device designed to distend the uterus by filling the uterine cavity with a liquid or gas to facilitate viewing with a hysteroscope.

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

(2) Class I for tubing and tubing/filter fits which only include accessory instruments that are not used to effect intrauterine access, e.g., hysteroscopic introducer sheaths, etc.; and single-use tubing kits used for only intrauterine insufflation. 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.


§ 884.1720 Gynecologic laparoscope and accessories.

(a) Identification. A gynecologic laparoscope is a device used to permit direct viewing of the organs within the peritoneum by a telescopic system introduced through the abdominal wall. 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 preheater, light source and cables, and component parts.

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

(2) Class I for gynecologic laparoscope accessories that are not part of a specialized instrument or device delivery system, do not have adapters, connector channels, or do not have portals for electrosurgical, lasers, or other power sources. Such gynecologic laparoscope accessory instruments include: the 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.


Subpart C—Obstetrical and Gynecological Monitoring Devices

§ 884.2050 Obstetric data analyzer.

(a) Identification. An obstetric data analyzer (fetal status data analyzer) is a device used during labor to analyze electronic signal data obtained from fetal and maternal monitors. The obstetric data analyzer provides clinical