

Food and Drug Administration, HHS

§ 862.1295

subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2306, Jan. 14, 2000]

§ 862.1270 Estrogens (total, in pregnancy) test system.

(a) *Identification.* As estrogens (total, in pregnancy) test system is a device intended to measure total estrogens in plasma, serum, and urine during pregnancy. The device primarily measures estrone plus estradiol. Measurements of total estrogens are used to aid in the diagnosis and treatment of fetoplacental distress in certain cases of high-risk pregnancy.

(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 § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2306, Jan. 14, 2000]

§ 862.1275 Estrogens (total, nonpregnancy) test system.

(a) *Identification.* As estrogens (total, nonpregnancy) test system is a device intended to measure the level of estrogens (total estrone, estradiol, and estriol) in plasma, serum, and urine of males and nonpregnant females. Measurement of estrogens (total, nonpregnancy) is used in the diagnosis and treatment of numerous disorders, including infertility, amenorrhea (absence of menses) differentiation of primary and secondary ovarian malfunction, estrogen secreting testicular and ovarian tumors, and precocious puberty in females.

(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 § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2306, Jan. 14, 2000]

§ 862.1280 Estrone test system.

(a) *Identification.* An estrone test system is a device intended to measure estrone, an estrogenic steroid, in plasma. Estrone measurements are used in the diagnosis and treatment of numerous disorders, including infertility, amenorrhea, differentiation of primary

and secondary ovarian malfunction, estrogen secreting testicular and ovarian tumors, and precocious puberty in females.

(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 § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2306, Jan. 14, 2000]

§ 862.1285 Etiocholanolone test system.

(a) *Identification.* An etiocholanolone test system is a device intended to measure etiocholanolone in serum and urine. Etiocholanolone is a metabolic product of the hormone testosterone and is excreted in the urine. Etiocholanolone measurements are used in the diagnosis and treatment of disorders of the testes and ovaries.

(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 § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2306, Jan. 14, 2000]

§ 862.1290 Fatty acids test system.

(a) *Identification.* A fatty acids test system is a device intended to measure fatty acids in plasma and serum. Measurements of fatty acids are used in the diagnosis and treatment of various disorders of lipid metabolism.

(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 § 862.9.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988; 66 FR 38787, July 25, 2001]

§ 862.1295 Folic acid test system.

(a) *Identification.* A folic acid test system is a device intended to measure the vitamin folic acid in plasma and serum. Folic acid measurements are used in the diagnosis and treatment of megaloblastic anemia, which is characterized by the presence of megaloblasts (an abnormal red blood cell series) in the bone marrow.