

§ 862.1150 Calibrator.

(a) *Identification.* A calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens. (See also § 862.2 in this part.)

(b) *Classification.* Class II.

§ 862.1155 Human chorionic gonadotropin (HCG) test system.

(a) *Human chorionic gonadotropin (HCG) test system intended for the early detection of pregnancy—(1) Identification.* A human chorionic gonadotropin (HCG) test system is a device intended for the early detection of pregnancy is intended to measure HCG, a placental hormone, in plasma or urine.

(2) *Classification.* Class II.

(b) *Human chorionic gonadotropin (HCG) test system intended for any uses other than early detection of pregnancy—*

(1) *Identification.* A human chorionic gonadotropin (HCG) test system is a device intended for any uses other than early detection of pregnancy (such as an aid in the diagnosis, prognosis, and management of treatment of persons with certain tumors or carcinomas) is intended to measure HCG, a placental hormone, in plasma or urine.

(2) *Classification.* Class III.

(3) *Date PMA or notice of completion of a PDP is required.* As of the enactment date of the amendments, May 28, 1976, an approval under section 515 of the act is required before the device described in paragraph (b)(1) may be commercially distributed. See § 862.3.

§ 862.1160 Bicarbonate/carbon dioxide test system.

(a) *Identification.* A bicarbonate/carbon dioxide test system is a device intended to measure bicarbonate/carbon dioxide in plasma, serum, and whole blood. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

(b) *Classification.* Class II.

§ 862.1165 Catecholamines (total) test system.

(a) *Identification.* A catecholamines (total) test system is a device intended to determine whether a group of similar compounds (epinephrine, norepinephrine, and dopamine) are present in urine and plasma. Catecholamine determinations are used in the diagnosis and treatment of adrenal medulla and hypertensive disorders, and for catecholamine-secreting tumors (pheochromocytoma, neuroblastoma, ganglioneuroma, and retinoblastoma).

(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 2305, Jan. 14, 2000]

§ 862.1170 Chloride test system.

(a) *Identification.* A chloride test system is a device intended to measure the level of chloride in plasma, serum, sweat, and urine. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

(b) *Classification.* Class II.

§ 862.1175 Cholesterol (total) test system.

(a) *Identification.* A cholesterol (total) test system is a device intended to measure cholesterol in plasma and serum. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.

(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 2305, Jan. 14, 2000]

§ 862.1177 Cholyglycine test system.

(a) *Identification.* A cholyglycine test system is a device intended to measure the bile acid cholyglycine in serum. Measurements obtained by this device

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are used in the diagnosis and treatment of liver disorders, such as cirrhosis or obstructive liver disease.

(b) *Classification.* Class II.

§ 862.1180 Chymotrypsin test system.

(a) *Identification.* A chymotrypsin test system is a device intended to measure the activity of the enzyme chymotrypsin in blood and other body fluids and in feces. Chymotrypsin measurements are used in the diagnosis and treatment of pancreatic exocrine insufficiency.

(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 2305, Jan. 14, 2000]

§ 862.1185 Compound S (11-deoxycortisol) test system.

(a) *Identification.* A compound S (11-dioxycortisol) test system is a device intended to measure the level of compound S (11-dioxycortisol) in plasma. Compound S is a steroid intermediate in the biosynthesis of the adrenal hormone cortisol. Measurements of compound S are used in the diagnosis and treatment of certain adrenal and pituitary gland disorders resulting in clinical symptoms of masculinization and hypertension.

(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 2305, Jan. 14, 2000]

§ 862.1187 Conjugated sulfolithocholic acid (SLCG) test system.

(a) *Identification.* A conjugated sulfolithocholic acid (SLCG) test system is a device intended to measure the bile acid SLCG in serum. Measurements obtained by this device are used in the diagnosis and treatment of liver disorders, such as cirrhosis or obstructive liver disease.

(b) *Classification.* Class II.

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§ 862.1190 Copper test system.

(a) *Identification.* A copper test system is a device intended to measure copper levels in plasma, serum, and urine. Measurements of copper are used in the diagnosis and treatment of anemia, infections, inflammations, and Wilson's disease (a hereditary disease primarily of the liver and nervous system). Test results are also used in monitoring patients with Hodgkin's disease (a disease primarily of the lymph system).

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

§ 862.1195 Corticoids test system.

(a) *Identification.* A corticoids test system is a device intended to measure the levels of corticoids (hormones of the adrenal cortex) in serum and plasma. Measurements of corticoids are used in the diagnosis and treatment of disorders of the cortex of the adrenal glands, especially those associated with hypertension and electrolyte disturbances.

(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 2305, Jan. 14, 2000]

§ 862.1200 Corticosterone test system.

(a) *Identification.* A corticosterone test system is a device intended to measure corticosterone (a steroid secreted by the adrenal gland) levels in plasma. Measurements of corticosterone are used in the diagnosis and treatment of adrenal disorders such as adrenal cortex disorders and blocks in cortisol synthesis.

(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 2305, Jan. 14, 2000]