

§ 862.1187

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.

§ 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 (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]

§ 862.1195 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

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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]

§ 862.1205 Cortisol (hydrocortisone and hydroxycorticosterone) test system.

(a) *Identification*. A cortisol (hydrocortisone and hydroxycorticosterone) test system is a device intended to measure the cortisol hormones secreted by the adrenal gland in plasma and urine. Measurements of cortisol are used in the diagnosis and treatment of disorders of the adrenal gland.

(b) *Classification*. Class II.

§ 862.1210 Creatine test system.

(a) *Identification*. A creatine test system is a device intended to measure creatine (a substance synthesized in the liver and pancreas and found in biological fluids) in plasma, serum, and urine. Measurements of creatine are used in the diagnosis and treatment of muscle diseases and endocrine disorders including hyperthyroidism.

(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]

§ 862.1215 Creatine phosphokinase/creatinine kinase or isoenzymes test system.

(a) *Identification.* A creatine phosphokinase/creatinine kinase or isoenzymes test system is a device intended to measure the activity of the enzyme creatine phosphokinase or its isoenzymes (a group of enzymes with similar biological activity) in plasma and serum. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

(b) *Classification.* Class II.

§ 862.1225 Creatinine test system.

(a) *Identification.* A creatinine test system is a device intended to measure creatinine levels in plasma and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

(b) *Classification.* Class II.

§ 862.1230 Cyclic AMP test system.

(a) *Identification.* A cyclic AMP test system is a device intended to measure the level of adenosine 3', 5'-monophosphate (cyclic AMP) in plasma, urine, and other body fluids. Cyclic AMP measurements are used in the diagnosis and treatment of endocrine disorders, including hyperparathyroidism (overactivity of the parathyroid gland). Cyclic AMP measurements may also be used in the diagnosis and treatment of Graves' disease (a disorder of the thyroid) and in the differentiation of causes of hypercalcemia (elevated levels of serum calcium.)

(b) *Classification.* Class II.

§ 862.1235 Cyclosporine test system.

(a) *Identification.* A cyclosporine test system is a device intended to quantitatively determine cyclosporine concentrations as an aid in the management of transplant patients receiving

therapy with this drug. This generic type of device includes immunoassays and chromatographic assays for cyclosporine.

(b) *Classification.* Class II (special controls). The special control is "Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA." See § 862.1(d) for the availability of this guidance document.

[67 FR 58329, Sept. 16, 2002]

§ 862.1240 Cystine test system.

(a) *Identification.* A cystine test system is a device intended to measure the amino acid cystine in urine. Cystine measurements are used in the diagnosis of cystinuria (occurrence of cystine in urine). Patients with cystinuria frequently develop kidney calculi (stones).

(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]

§ 862.1245 Dehydroepiandrosterone (free and sulfate) test system.

(a) *Identification.* A dehydroepiandrosterone (free and sulfate) test system is a device intended to measure dehydroepiandrosterone (DHEA) and its sulfate in urine, serum, plasma, and amniotic fluid. Dehydroepiandrosterone measurements are used in the diagnosis and treatment of DHEA-secreting adrenal carcinomas.

(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]

§ 862.1250 Desoxycorticosterone test system.

(a) *Identification.* A desoxycorticosterone test system is a device intended to measure desoxycorticosterone (DOC) in plasma and urine. DOC measurements are used