

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]

§ 862.1335 Glucagon test system.

(a) *Identification.* A glucagon test system is a device intended to measure the pancreatic hormone glucagon in plasma and serum. Glucagon measurements are used in the diagnosis and treatment of patients with various disorders of carbohydrate metabolism, including diabetes mellitus, hypoglycemia, and hyperglycemia.

(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]

§ 862.1340 Urinary glucose (non-quantitative) test system.

(a) *Identification.* A urinary glucose (nonquantitative) test system is a device intended to measure glucosuria (glucose in urine). Urinary glucose (nonquantitative) measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, hypoglycemia, and hyperglycemia.

(b) *Classification.* Class II.

§ 862.1345 Glucose test system.

(a) *Identification.* A glucose test system is a device intended to measure glucose quantitatively in blood and other body fluids. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

(b) *Classification.* Class II.

§ 862.1360 Gamma-glutamyl transpeptidase and isoenzymes test system.

(a) *Identification.* A gamma-glutamyl transpeptidase and isoenzymes test system is a device intended to measure the activity of the enzyme gamma-glutamyl transpeptidase (GGTP) in plasma and serum. Gamma-glutamyl

transpeptidase and isoenzymes measurements are used in the diagnosis and treatment of liver diseases such as alcoholic cirrhosis and primary and secondary liver tumors.

(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]

§ 862.1365 Glutathione test system.

(a) *Identification.* A glutathione test system is a device intended to measure glutathione (the tripeptide of glycine, cysteine, and glutamic acid) in erythrocytes (red blood cells). Glutathione measurements are used in the diagnosis and treatment of certain drug-induced hemolytic (erythrocyte destroying) anemias due to an inherited enzyme deficiency.

(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]

§ 862.1370 Human growth hormone test system.

(a) *Identification.* A human growth hormone test system is a device intended to measure the levels of human growth hormone in plasma. Human growth hormone measurements are used in the diagnosis and treatment of disorders involving the anterior lobe of the pituitary gland.

(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]

§ 862.1375 Histidine test system.

(a) *Identification.* A histidine test system is a device intended to measure free histidine (an amino acid) in plasma and urine. Histidine measurements

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are used in the diagnosis and treatment of hereditary histidinemia characterized by excess histidine in the blood and urine often resulting in mental retardation and disordered speech development.

(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]

§ 862.1377 **Urinary homocystine (non-quantitative) test system.**

(a) *Identification.* A urinary homocystine (nonquantitative) test system is a device intended to identify homocystine (an analogue of the amino acid cystine) in urine. The identification of urinary homocystine is used in the diagnosis and treatment of homocystinuria (homocystine in urine), a heritable metabolic disorder which may cause mental retardation.

(b) *Classification.* Class II.

§ 862.1380 **Hydroxybutyric dehydrogenase test system.**

(a) *Identification.* A hydroxybutyric dehydrogenase test system is a device intended to measure the activity of the enzyme alpha-hydroxybutyric dehydrogenase (HBD) in plasma or serum. HBD measurements are used in the diagnosis and treatment of myocardial infarction, renal damage (such as rejection of transplants), certain hematological diseases (such as acute leukemias and megaloblastic anemias) and, to a lesser degree, liver disease.

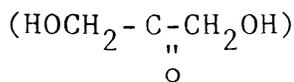
(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

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

§ 862.1385 **17-Hydroxycorticosteroids (17-ketogenic steroids) test system.**

(a) *Identification.* A 17-hydroxycorticosteroids (17-ketogenic steroids) test system is a device intended to measure corticosteroids that possess a dihydroxyacetone

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moiety on the steroid nucleus in urine. Corticosteroids with this chemical configuration include cortisol, cortisone 11-desoxycortisol, desoxycorticosterone, and their tetrahydroderivatives. This group of hormones is synthesized by the adrenal gland. Measurements of 17-hydroxycorticosteroids (17-ketogenic steroids) are used in the diagnosis and treatment of various diseases of the adrenal or pituitary glands and gonadal 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; 52 FR 29468, Aug. 7, 1987, as amended at 65 FR 2306, Jan. 14, 2000]

§ 862.1390 **5-Hydroxyindole acetic acid/serotonin test system.**

(a) *Identification.* A 5-hydroxyindole acetic acid/serotonin test system is a device intended to measure 5-hydroxyindole acetic acid/serotonin in urine. Measurements of 5-hydroxyindole acetic acid/serotonin are used in the diagnosis and treatment of carcinoid tumors of endocrine tissue.

(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]

§ 862.1395 **17-Hydroxyprogesterone test system.**

(a) *Identification.* A 17-hydroxyprogesterone test system is a device intended to measure 17-hydroxyprogesterone (a steroid) in plasma and serum. Measurements of 17-hydroxyprogesterone are used in the diagnosis and treatment of various disorders of the adrenal glands or the ovaries.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in