

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.

[52 FR 16122, May 1, 1987; 52 FR 29468, Aug. 7, 1987]

§ 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.

§ 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.

§ 862.1400 Hydroxyproline test system.

(a) *Identification.* A hydroxyproline test system is a device intended to measure the amino acid hydroxyproline in urine. Hydroxyproline measurements are used in the diagnosis and treatment of various collagen (connective tissue) diseases, bone disease such as Paget's disease, and endocrine disorders such as hyperparathyroidism and hyperthyroidism.

(b) *Classification.* Class I.

§ 862.1405 Immunoreactive insulin test system.

(a) *Identification.* An immunoreactive insulin test system is a device intended to measure immunoreactive insulin in serum and plasma. Immunoreactive in-

sulin measurements are used in the diagnosis and treatment of various carbohydrate metabolism disorders, including diabetes mellitus, and hypoglycemia.

(b) *Classification.* Class I.

§ 862.1410 Iron (non-heme) test system.

(a) *Identification.* An iron (non-heme) test system is a device intended to measure iron (non-heme) in serum and plasma. Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease.

(b) *Classification.* Class I.

§ 862.1415 Iron-binding capacity test system.

(a) *Identification.* An iron-binding capacity test system is a device intended to measure iron-binding capacity in serum. Iron-binding capacity measurements are used in the diagnosis and treatment of anemia.

(b) *Classification.* Class I.

§ 862.1420 Isocitric dehydrogenase test system.

(a) *Identification.* An isocitric dehydrogenase test system is a device intended to measure the activity of the enzyme isocitric dehydrogenase in serum and plasma. Isocitric dehydrogenase measurements are used in the diagnosis and treatment of liver disease such as viral hepatitis, cirrhosis, or acute inflammation of the biliary tract; pulmonary disease such as pulmonary infarction (local arrest or sudden insufficiency of the blood supply to the lungs), and diseases associated with pregnancy.

(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]

§ 862.1430 17-Ketosteroids test system.

(a) *Identification.* A 17-ketosteroids test system is a device intended to

measure 17-ketosteroids in urine. Measurements of 17-ketosteroids are used in the diagnosis and treatment of disorders of the adrenal cortex and gonads and of other endocrine disorders, including hypertension, diabetes, and hypothyroidism.

(b) *Classification.* Class I.

§ 862.1435 Ketones (nonquantitative) test system.

(a) *Identification.* A ketones (non-quantitative) test system is a device intended to identify ketones in urine and other body fluids. Identification of ketones is used in the diagnosis and treatment of acidosis (a condition characterized by abnormally high acidity of body fluids) or ketosis (a condition characterized by increased production of ketone bodies such as acetone) and for monitoring patients on ketogenic diets and patients with diabetes.

(b) *Classification.* Class I.

§ 862.1440 Lactate dehydrogenase test system.

(a) *Identification.* A lactate dehydrogenase test system is a device intended to measure the activity of the enzyme lactate dehydrogenase in serum. Lactate dehydrogenase measurements are used in the diagnosis and treatment of liver diseases such as acute viral hepatitis, cirrhosis, and metastatic carcinoma of the liver, cardiac diseases such as myocardial infarction, and tumors of the lung or kidneys.

(b) *Classification.* Class II.

§ 862.1445 Lactate dehydrogenase isoenzymes test system.

(a) *Identification.* A lactate dehydrogenase isoenzymes test system is a device intended to measure the activity of lactate dehydrogenase isoenzymes (a group of enzymes with similar biological activity) in serum. Measurements of lactate dehydrogenase isoenzymes are used in the diagnosis and treatment of liver diseases, such as viral hepatitis, and myocardial infarction.

(b) *Classification.* Class II.

§ 862.1450 Lactic acid test system.

(a) *Identification.* A lactic acid test system is a device intended to measure lactic acid in whole blood and plasma.

Lactic acid measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

(b) *Classification.* Class I.

§ 862.1455 Lecithin/sphingomyelin ratio in amniotic fluid test system.

(a) *Identification.* A lecithin/sphingomyelin ratio in amniotic fluid test system is a device intended to measure the lecithin/sphingomyelin ratio in amniotic fluid. Lecithin and sphingomyelin are phospholipids (fats or fat-like substances containing phosphorus). Measurements of the lecithin/sphingomyelin ratio in amniotic fluid are used in evaluating fetal maturity.

(b) *Classification.* Class II.

§ 862.1460 Leucine aminopeptidase test system.

(a) *Identification.* A leucine aminopeptidase test system is a device intended to measure the activity of the enzyme leucine aminopeptidase in serum, plasma, and urine. Leucine aminopeptidase measurements are used in the diagnosis and treatment of liver diseases such as viral hepatitis and obstructive jaundice.

(b) *Classification.* Class I.

§ 862.1465 Lipase test system.

(a) *Identification.* A lipase test system is a device intended to measure the activity of the enzymes lipase in serum. Lipase measurements are used in diagnosis and treatment of diseases of the pancreas such as acute pancreatitis and obstruction of the pancreatic duct.

(b) *Classification.* Class I.

§ 862.1470 Lipid (total) test system.

(a) *Identification.* A lipid (total) test system is a device intended to measure total lipids (fats or fat-like substances) in serum and plasma. Lipid (total) measurements are used in the diagnosis and treatment of various diseases involving lipid metabolism and atherosclerosis.

(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]