

**§ 862.1475 Lipoprotein test system.**

(a) *Identification.* A lipoprotein test system is a device intended to measure lipoprotein in serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

(b) *Classification.* Class I.

**§ 862.1485 Luteinizing hormone test system.**

(a) *Identification.* A luteinizing hormone test system is a device intended to measure luteinizing hormone in serum and urine. Luteinizing hormone measurements are used in the diagnosis and treatment of gonadal dysfunction.

(b) *Classification.* Class I.

**§ 862.1490 Lysozyme (muramidase) test system.**

(a) *Identification.* A lysozyme (muramidase) test system is a device intended to measure the activity of the bacteriolytic enzyme lysozyme (muramidase) in serum, plasma, leukocytes, and urine. Lysozyme measurements are used in the diagnosis and treatment of monocytic leukemia and kidney disease.

(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]

**§ 862.1495 Magnesium test system.**

(a) *Identification.* A magnesium test system is a device intended to measure magnesium levels in serum and plasma. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium).

(b) *Classification.* Class I.

**§ 862.1500 Malic dehydrogenase test system.**

(a) *Identification.* A malic dehydrogenase test system is a device that is intended to measure the activity of the enzyme malic dehydrogenase in serum

and plasma. Malic dehydrogenase measurements are used in the diagnosis and treatment of muscle and liver diseases, myocardial infarctions, cancer, and blood disorders such as myelogenous (produced in the bone marrow) leukemia.

(b) *Classification.* Class I.

**§ 862.1505 Mucopolysaccharides (non-quantitative) test system.**

(a) *Identification.* A mucopolysaccharides (nonquantitative) test system is a device intended to measure the levels of mucopolysaccharides in urine. Mucopolysaccharide measurements in urine are used in the diagnosis and treatment of various inheritable disorders that affect bone and connective tissues, such as Hurler's, Hunter's, Sanfilippo's, Scheie's Morquio's and Maroteaux-Lamy syndromes.

(b) *Classification.* Class I.

**§ 862.1509 Methylmalonic acid (non-quantitative) test system.**

(a) *Identification.* A methylmalonic acid (nonquantitative) test system is a device intended to identify methylmalonic acid in urine. The identification of methylmalonic acid in urine is used in the diagnosis and treatment of methylmalonic aciduria, a heritable metabolic disorder which, if untreated, may cause mental retardation.

(b) *Classification.* Class II.

**§ 862.1510 Nitrite (nonquantitative) test system.**

(a) *Identification.* A nitrite (nonquantitative) test system is a device intended to identify nitrite in urine. Nitrite identification is used in the diagnosis and treatment of urinary tract infection of bacterial origin.

(b) *Classification.* Class I.

**§ 862.1515 Nitrogen (amino-nitrogen) test system.**

(a) *Identification.* A nitrogen (amino-nitrogen) test system is a device intended to measure amino acid nitrogen levels in serum, plasma, and urine. Nitrogen (amino-nitrogen) measurements are used in the diagnosis and treatment of certain forms of severe liver disease and renal disorders.

§ 862.1520

(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]

**§ 862.1520 5'-Nucleotidase test system.**

(a) *Identification.* A 5'-nucleotidase test system is a device intended to measure the activity of the enzyme 5'-nucleotidase in serum and plasma. Measurements of 5'-nucleotidase are used in the diagnosis and treatment of liver diseases and in the differentiations between liver and bone diseases in the presence of elevated serum alkaline phosphatase activity.

(b) *Classification.* Class I.

**§ 862.1530 Plasma oncometry test system.**

(a) *Identification.* A plasma oncometry test system is a device intended to measure plasma oncotic pressure. Plasma oncotic pressure is that portion of the total fluid pressure contributed by proteins and other molecules too large to pass through a specified membrane. Measurements of plasma oncotic pressure are used in the diagnosis and treatment of dehydration and circulatory disorders related to low serum protein levels and increased capillary permeability, such as edema and shock.

(b) *Classification.* Class I.

**§ 862.1535 Ornithine carbamyl transferase test system.**

(a) *Identification.* An ornithine carbamyl transferase test system is a device intended to measure the activity of the enzyme ornithine carbamyl transferase (OCT) in serum. Ornithine carbamyl transferase measurements are used in the diagnosis and treatment of liver diseases, such as infectious hepatitis, acute cholecystitis (inflammation of the gall bladder), cirrhosis, and liver metastases.

(b) *Classification.* Class I.

**§ 862.1540 Osmolality test system.**

(a) *Identification.* An osmolality test system is a device intended to measure ionic and nonionic solute concentration in body fluids, such as serum and urine. Osmolality measurement is used

21 CFR Ch. I (4–1–98 Edition)

as an adjunct to other tests in the evaluation of a variety of diseases, including kidney diseases (e.g., chronic progressive renal failure), diabetes insipidus, other endocrine and metabolic disorders, and fluid imbalances.

(b) *Classification.* Class I.

**§ 862.1542 Oxalate test system.**

(a) *Identification.* An oxalate test system is a device intended to measure the concentration of oxalate in urine. Measurements of oxalate are used to aid in the diagnosis or treatment of urinary stones or certain other metabolic disorders.

(b) *Classification.* Class I.

**§ 862.1545 Parathyroid hormone test system.**

(a) *Identification.* A parathyroid hormone test system is a device intended to measure the levels of parathyroid hormone in serum and plasma. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia (abnormally high levels of calcium in the blood) and hypocalcemia (abnormally low levels of calcium in the blood) resulting from disorders of calcium metabolism.

(b) *Classification.* Class II.

**§ 862.1550 Urinary pH (nonquantitative) test system.**

(a) *Identification.* A urinary pH (nonquantitative) test system is a device intended to estimate the pH of urine. Estimations of pH are used to evaluate the acidity or alkalinity of urine as it relates to numerous renal and metabolic disorders and in the monitoring of patients with certain diets.

(b) *Classification.* Class I.

**§ 862.1555 Phenylalanine test system.**

(a) *Identification.* A phenylalanine test system is a device intended to measure free phenylalanine (an amino acid) in serum, plasma, and urine. Measurements of phenylalanine are used in the diagnosis and treatment of congenital phenylketonuria which, if untreated, may cause mental retardation.

(b) *Classification.* Class II.