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

§ 862.1500 Malic dehydrogenase test system.

(a) Identification. A malic dehydrogenase test system is a device 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 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1505 Mucopolysaccharides (nonquantitative) 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 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1509 Methylmalonic acid (nonquantitative) 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 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 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.

(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.