Food and Drug Administration, HHS § 862.1505

§ 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 (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 21449, June 8, 1988; 66 FR 38788, July 25, 2001]

§ 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 (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 21449, June 8, 1988; 66 FR 38788, July 25, 2001]

§ 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.

[52 FR 21449, June 8, 1988; 66 FR 38788, July 25, 2001]

§ 862.1505 Mucopolysaccharides (nonquantitative) test system.

(a) Identification. A mucopolysaccharides (nonquantitative) test system is a device intended to measure the activity of the enzyme mucopolysaccharides in serum and urine. Mucopolysaccharide measurements are used in the diagnosis and treatment of various diseases involving lipid metabolism and atherosclerosis.

(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.