§ 862.1440 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 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §862.9.


§ 862.1445 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.

§ 862.1450 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 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §862.9.


§ 862.1455 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 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §862.9.
§ 862.1470 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 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

§ 862.1475 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 § 862.9.

§ 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.

§ 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 monocyctic leukemia and kidney 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 § 862.9.

§ 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.