§ 862.1187 Corticoids test system.

(a) Identification. A corticoids test system is a device intended to measure the levels of corticoids (hormones of the adrenal cortex) in serum and plasma. Measurements of corticoids are used in the diagnosis and treatment of disorders of the cortex of the adrenal glands, especially those associated with hypertension and electrolyte disturbances.

(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.


§ 862.1210 Creatine test system.

(a) Identification. A creatine test system is a device intended to measure creatine (a substance synthesized in the liver and pancreas and found in biological fluids) in plasma, serum, and urine. Measurements of creatine are used in the diagnosis and treatment of muscle diseases and endocrine disorders including hyperthyroidism.

(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.