intended to measure the level of compound S (11-dioxycortisol) in plasma. Compound S is a steroid intermediate in the biosynthesis of the adrenal hormone cortisol. Measurements of compound S are used in the diagnosis and treatment of certain adrenal and pituitary gland disorders resulting in clinical symptoms of masculinization and hypertension.

(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.


§ 862.1187 Conjugated sulfolithocholic acid (SLCG) test system.

(a) Identification. A conjugated sulfolithocholic acid (SLCG) test system is a device intended to measure the bile acid SLCG in serum. Measurements obtained by this device are used in the diagnosis and treatment of liver disorders, such as cirrhosis or obstructive liver disease.

(b) Classification. Class II.

§ 862.1190 Copper test system.

(a) Identification. A copper test system is a device intended to measure copper levels in plasma, serum, and urine. Measurements of copper are used in the diagnosis and treatment of anemia, infections, inflammations, and Wilson’s disease (a hereditary disease primarily of the liver and nervous system). Test results are also used in monitoring patients with Hodgkin’s disease (a disease primarily of the lymph system).

(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.


§ 862.1195 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