§ 862.1060 Delta-aminolevulinic acid test system.

(a) Identification. A delta-aminolevulinic acid test system is a device intended to measure the level of delta-aminolevulinic acid (a precursor of porphyrin) in urine. Delta-aminolevulinic acid measurements are used in the diagnosis and treatment of lead poisoning and certain porphyrias (diseases affecting the liver, gastrointestinal, and nervous systems that are accompanied by increased urinary excretion of various heme compounds including delta-aminolevulinic acid).

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


§ 862.1080 Androsterone test system.

(a) Identification. An androsterone test system is a device intended to measure the hormone adrosterone in serum, plasma, and urine. Androsterone measurements are used in the diagnosis and treatment of gonadal and adrenal 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.


§ 862.1090 Angiotensin converting enzyme (A.C.E.) test system.

(a) Identification. An angiotensin converting enzyme (A.C.E.) test system is a device intended to measure the activity of angiotensin converting enzyme in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of diseases such as sarcoidosis, a disease characterized by the formation of nodules in the lungs, bones, and skin, and Gaucher’s disease, a hereditary disorder affecting the spleen.

(b) Classification. Class II.

§ 862.1095 Ascorbic acid test system.

(a) Identification. An ascorbic acid test system is a device intended to measure the level of ascorbic acid (vitamin C) in plasma, serum, and urine. Ascorbic acid measurements are used in the diagnosis and treatment of ascorbic acid dietary deficiencies.

(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.