§ 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.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2305, Jan. 14, 2000]

§ 862.1065 Ammonia test system.

(a) *Identification.* An ammonia test system is a device intended to measure ammonia levels in blood, serum, and plasma, Ammonia measurements are used in the diagnosis and treatment of severe liver disorders, such as cirrhosis, hepatitis, and Reye's syndrome.

(b) *Classification.* Class I.

§ 862.1070 Amylase test system.

(a) *Identification.* An amylase test system is a device intended to measure the activity of the enzyme amylase in serum and urine. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas).

(b) *Classification.* Class II.

§ 862.1075 Androstenedione test system.

(a) *Identification.* An androstenedione test system is a device intended to measure androstenedione (a substance secreted by the testes, ovary, and adrenal glands) in serum. Adrostenedione measurements are used in the diagnosis and treatment of females with excessive levels of androgen (male sex hormone) production.

(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 16122, May 1, 1987, as amended at 65 FR 2305, Jan. 14, 2000]

§ 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.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2305, Jan. 14, 2000]

§ 862.1085 Angiotensin I and renin test system.

(a) *Identification.* An angiotensin I and renin test system is a device intended to measure the level of angiotensin I generated by renin in plasma. Angiotensin I measurements are used in the diagnosis and treatment of certain types of hypertension.

(b) *Classification.* Class II.

§ 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