

§ 862.1215

subpart E of part 807 of this chapter subject to the limitations in § 862.9.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988; 66 FR 38787, July 25, 2001]

§ 862.1215 Creatine phosphokinase/creatinine kinase or isoenzymes test system.

(a) *Identification.* A creatine phosphokinase/creatinine kinase or isoenzymes test system is a device intended to measure the activity of the enzyme creatine phosphokinase or its isoenzymes (a group of enzymes with similar biological activity) in plasma and serum. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

(b) *Classification.* Class II.

§ 862.1225 Creatinine test system.

(a) *Identification.* A creatinine test system is a device intended to measure creatinine levels in plasma and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

(b) *Classification.* Class II.

§ 862.1230 Cyclic AMP test system.

(a) *Identification.* A cyclic AMP test system is a device intended to measure the level of adenosine 3', 5'-monophosphate (cyclic AMP) in plasma, urine, and other body fluids. Cyclic AMP measurements are used in the diagnosis and treatment of endocrine disorders, including hyperparathyroidism (overactivity of the parathyroid gland). Cyclic AMP measurements may also be used in the diagnosis and treatment of Graves' disease (a disorder of the thyroid) and in the differentiation of causes of hypercalcemia (elevated levels of serum calcium.)

(b) *Classification.* Class II.

§ 862.1235 Cyclosporine test system.

(a) *Identification.* A cyclosporine test system is a device intended to quantitatively determine cyclosporine concentrations as an aid in the management of transplant patients receiving

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therapy with this drug. This generic type of device includes immunoassays and chromatographic assays for cyclosporine.

(b) *Classification.* Class II (special controls). The special control is "Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA." See § 862.1(d) for the availability of this guidance document.

[67 FR 58329, Sept. 16, 2002]

§ 862.1240 Cystine test system.

(a) *Identification.* A cystine test system is a device intended to measure the amino acid cystine in urine. Cystine measurements are used in the diagnosis of cystinuria (occurrence of cystine in urine). Patients with cystinuria frequently develop kidney calculi (stones).

(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]

§ 862.1245 Dehydroepiandrosterone (free and sulfate) test system.

(a) *Identification.* A dehydroepiandrosterone (free and sulfate) test system is a device intended to measure dehydroepiandrosterone (DHEA) and its sulfate in urine, serum, plasma, and amniotic fluid. Dehydroepiandrosterone measurements are used in the diagnosis and treatment of DHEA-secreting adrenal carcinomas.

(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 2306, Jan. 14, 2000]

§ 862.1250 Desoxycorticosterone test system.

(a) *Identification.* A desoxycorticosterone test system is a device intended to measure desoxycorticosterone (DOC) in plasma and urine. DOC measurements are used