

§ 862.1117

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]

§ 862.1117 B-type natriuretic peptide test system.

(a) *Identification.* The B-type natriuretic peptide (BNP) test system is an in vitro diagnostic device intended to measure BNP in whole blood and plasma. Measurements of BNP are used as an aid in the diagnosis of patients with congestive heart failure.

(b) *Classification.* Class II (special controls). The special control is "Class II Special Control Guidance Document for B-Type Natriuretic Peptide Pre-market Notifications; Final Guidance for Industry and FDA Reviewers."

[66 FR 12734, Feb. 28, 2001]

§ 862.1118 Biotinidase test system.

(a) *Identification.* The biotinidase test system is an in vitro diagnostic device intended to measure the activity of the enzyme biotinidase in blood. Measurements of biotinidase are used in the treatment and diagnosis of biotinidase deficiency, an inborn error of metabolism in infants, characterized by the inability to utilize dietary protein bound vitamin or to recycle endogenous biotin. The deficiency may result in irreversible neurological impairment.

(b) *Classification.* Class II (special controls). The special control is sale, distribution, and use in accordance with the prescription device requirements in § 801.109 of this chapter.

[65 FR 16521, Mar. 29, 2000]

§ 862.1120 Blood gases (P_{CO2}, P_{O2}) and blood pH test system.

(a) *Identification.* A blood gases (P_{CO2}, P_{O2}) and blood pH test system is a device intended to measure certain gases in blood, serum, plasma or pH of blood, serum, and plasma. Measurements of blood gases (P_{CO2}, P_{O2}) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances.

(b) *Classification.* Class II.

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§ 862.1130 Blood volume test system.

(a) *Identification.* A blood volume test system is a device intended to measure the circulating blood volume. Blood volume measurements are used in the diagnosis and treatment of shock, hemorrhage, and polycythemia vera (a disease characterized by an absolute increase in erythrocyte mass and total blood volume).

(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]

§ 862.1135 C-peptides of proinsulin test system.

(a) *Identification.* A C-peptides of proinsulin test system is a device intended to measure C-peptides of proinsulin levels in serum, plasma, and urine. Measurements of C-peptides of proinsulin are used in the diagnosis and treatment of patients with abnormal insulin secretion, including diabetes mellitus.

(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]

§ 862.1140 Calcitonin test system.

(a) *Identification.* A calcitonin test system is a device intended to measure the thyroid hormone calcitonin (thyrocalcitonin) levels in plasma and serum. Calcitonin measurements are used in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism (excessive activity of the parathyroid gland).

(b) *Classification.* Class II.

§ 862.1145 Calcium test system.

(a) *Identification.* A calcium test system is a device intended to measure the total calcium level in serum. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases,