§ 862.1325 Gastrin test system.

(a) Identification. A gastrin test system is a device intended to measure the hormone gastrin in plasma and serum. Measurements of gastrin are used in the diagnosis and treatment of patients with ulcers, pernicious anemia, and the Zollinger-Ellison syndrome (peptic ulcer due to a gastrin-secreting tumor of the pancreas).

(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.

§ 862.1335 Glucagon test system.

(a) Identification. A glucagon test system is a device intended to measure the pancreatic hormone glucagon in plasma and serum. Glucagon measurements are used in the diagnosis and treatment of patients with various disorders of carbohydrate metabolism, including diabetes mellitus, hypoglycemia, and hyperglycemia.

(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.

§ 862.1345 Glucose test system.

(a) Identification. A glucose test system is a device intended to measure glucose quantitatively in blood and other body fluids. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

(b) Classification. Class II.

§ 862.1360 Gamma-glutamyl transpeptidase and isoenzymes test system.

(a) Identification. A gamma-glutamyl transpeptidase and isoenzymes test system is a device intended to measure the activity of the enzyme gamma-glutamyl transpeptidase (GGTP) in plasma and serum. Gamma-glutamyl transpeptidase and isoenzymes measurements are used in the diagnosis and treatment of liver diseases such as alcoholic cirrhosis and primary and secondary liver tumors.

(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.