Food and Drug Administration, HHS

§ 862.1415 Iron-binding capacity test system.
(a) Identification. An iron-binding capacity test system is a device intended to measure iron-binding capacity in serum. Iron-binding capacity measurements are used in the diagnosis and treatment of anemia.
(b) Classification. Class I.

§ 862.1410 Iron (non-heme) test system.
(a) Identification. An iron (non-heme) test system is a device intended to measure iron (non-heme) in serum and plasma. Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease.
(b) Classification. Class I.

§ 862.1400 Hydroxyproline test system.
(a) Identification. A hydroxyproline test system is a device intended to measure the amino acid hydroxyproline in urine. Hydroxyproline measurements are used in the diagnosis and treatment of various collagen (connective tissue) diseases, bone disease such as Paget’s disease, and endocrine disorders such as hyperparathyroidism and hyperthyroidism.
(b) Classification. Class I.

§ 862.1395 17-Hydroxyprogesterone test system.
(a) Identification. A 17-hydroxyprogesterone test system is a device intended to measure 17-hydroxyprogesterone (a steroid) in plasma and serum. Measurements of 17-hydroxyprogesterone are used in the diagnosis and treatment of various disorders of the adrenal glands or the ovaries.
(b) Classification. Class I.

§ 862.1390 5-Hydroxyindole acetic acid/serotonin test system.
(a) Identification. A 5-hydroxyindole acetic acid/serotonin test system is a device intended to measure 5-hydroxyindole acetic acid/serotonin in urine. Measurements of 5-hydroxyindole acetic acid/serotonin are used in the diagnosis and treatment of carcinoid tumors of endocrine tissue.
(b) Classification. Class I.

§ 862.1405 Immunoreactive insulin test system.
(a) Identification. An immunoreactive insulin test system is a device intended to measure immunoreactive insulin in serum and plasma. Immunoreactive insulin measurements are used in the diagnosis and treatment of various carbohydrate metabolism disorders, including diabetes mellitus, and hypoglycemia.
(b) Classification. Class I.

§ 862.1400 Iron (non-heme) test system.
(a) Identification. An iron (non-heme) test system is a device intended to measure iron (non-heme) in serum and plasma. Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease.
(b) Classification. Class I.

§ 862.1415 Iron-binding capacity test system.
(a) Identification. An iron-binding capacity test system is a device intended to measure iron-binding capacity in serum. Iron-binding capacity measurements are used in the diagnosis and treatment of anemia.
(b) Classification. Class I.