§ 866.5460 Haptoglobin immunological test system.

(a) Identification. A haptoglobin immunological test system is a device that consists of the reagents used to measure by immunochromatography the haptoglobin (a protein that binds hemoglobin, the oxygen-carrying pigment in red blood cells) in serum. Measurement of haptoglobin may aid in the diagnosis of hemolytic diseases (diseases in which the red blood cells rupture and release hemoglobin) related to the formation of hemoglobin-haptoglobin complexes and certain kidney diseases.

(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 63 FR 59227, Nov. 3, 1998]

§ 866.5500 Hypersensitivity pneumonitis immunological test system.

(a) Identification. A hypersensitivity pneumonitis immunological test system is a device that consists of the reagents used to measure by immunochromatography the immunoglobulin antibodies in serum which react specifically with organic dust derived from fungal or animal protein sources. When these antibodies react with such dusts in the lung, immune complexes precipitate and trigger an inflammatory reaction (hypersensitivity pneumonitis). Measurement of these immunoglobulin G antibodies aids in the diagnosis of hypersensitivity pneumonitis and other allergic respiratory disorders.

(b) Classification. Class II (performance standards).

§ 866.5510 Immunoglobulins A, G, M, D, and E immunological test system.

(a) Identification. An immunoglobulins A, G, M, D, and E immunological test system is a device that consists of the reagents used to measure by immunochromatography the immunoglobulins A, G, M, D, and E (serum antibodies) in serum. Measurement of these immunoglobulins aids in the diagnosis of abnormal protein metabolism and the body’s lack of ability to resist infectious agents.

(b) Classification. Class II (performance standards).

§ 866.5520 Immunoglobulin G (Fab fragment specific) immunological test system.

(a) Identification. An immunoglobulin G (Fab fragment specific) immunological test system is a device that consists of the reagents used to measure by immunochromatography the Fab antigen-binding fragment resulting from breakdown of