§ 866.5590 Lipoprotein X immunological test system.

(a) Identification. A lipoprotein X immunological test system is a device that consists of the reagents used to measure by immunoochemical techniques lipoprotein X (a high-density lipoprotein) in serum and other body fluids. Measurement of lipoprotein X aids in the diagnosis of obstructive liver disease.

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

§ 866.5600 Low-density lipoprotein immunological test system.

(a) Identification. A low-density lipoprotein immunological test system is a device that consists of the reagents used to measure by immunoochemical techniques the low-density lipoprotein in serum and other body fluids. Measurement of low-density lipoprotein in serum may aid in the diagnosis of disorders of lipid (fat) metabolism and help to identify young persons at risk from cardiovascular disease.

(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 §866.9.


§ 866.5620 Alpha-2-macroglobulin immunological test system.

(a) Identification. An alpha-2-macroglobulin immunological test system is a device that consists of the reagents used to measure by immunoochemical techniques the alpha-2-macroglobulin (a serum protein) in plasma. Measurement of alpha-2-macroglobulin may aid in the diagnosis of blood-clotting or clot lysis disorders.

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

§ 866.5640 Infectious mononucleosis immunological test system.

(a) Identification. An infectious mononucleosis immunological test system is a device that consists of the reagents used to measure by immunoochemical techniques heterophile antibodies frequently associated with infectious mononucleosis in serum, plasma, and other body fluids. Measurements of these antibodies aid in the diagnosis of infectious mononucleosis.

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

[47 FR 50823, Nov. 9, 1982; 47 FR 56846, Dec. 21, 1982]

§ 866.5660 Myoglobin immunological test system.

(a) Identification. A myoglobin immunological test system is a device that consists of the reagents used to measure by immunoochemical techniques the myoglobin (an oxygen storage protein found in muscle) in serum and other body fluids. Measurement of