§ 866.5580  
Milk, other body fluids, and tissues. Measurement of lactoferrin may aid in the diagnosis of an inherited deficiency of this protein.

(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.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2312, Jan. 14, 2000]

§ 866.5580  
Alpha-1-lipoprotein immunological test system.

(a) Identification. An alpha-1-lipoprotein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha-1-lipoprotein (high-density lipoprotein) in serum and plasma. Measurement of alpha-1-lipoprotein may aid in the diagnosis of Tangier disease (a hereditary disorder of fat metabolism).

(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.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2312, Jan. 14, 2000]

§ 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 immunochemical 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 immunochemical 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 diseases.

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

§ 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 immunochemical 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).

§ 866.5630  
Beta-2-microglobulin immunological test system.

(a) Identification. A beta-2-microglobulin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques beta-2-microglobulin (a protein molecule) in serum, urine, and other body fluids. Measurement of beta-2-microglobulin aids in the diagnosis of active rheumatoid arthritis and kidney disease.

(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 immunochemical 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).

§ 866.5660  
Multiple autoantibodies immunological test system.

(a) Identification. A multiple autoantibodies immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoantibodies (antibodies produced against the body's own tissues) in