immunochemical techniques the complement C1 inhibitor (a plasma protein) in serum. Complement C1 inhibitor occurs normally in plasma and blocks the action of the C1 component of complement (a group of serum proteins which destroy infectious agents). Measurement of complement C1 inhibitor aids in the diagnosis of hereditary angioneurotic edema (increased blood vessel permeability causing swelling of tissues) and a rare form of angioedema associated with lymphoma (lymph node cancer).

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

§ 866.5260 Complement C3b inactivator immunological test system.

(a) **Identification.** A complement C3b inactivator immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the complement C3b inactivator (a plasma protein) in serum. Complement is a group of serum proteins that destroy infectious agents. Measurement of complement C3b inactivator aids in the diagnosis of inherited antibody dysfunction.

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

§ 866.5270 C-reactive protein immunological test system.

(a) **Identification.** A C-reactive protein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the C-reactive protein in serum and other body fluids. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues.

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

§ 866.5320 Properdin factor B immunological test system.

(a) **Identification.** A properdin factor B immunological test system is a device that consists of the reagents used to measure by immunochemical techniques properdin factor B in serum and other body fluids. The deposition of properdin factor B in body tissues or a corresponding depression in the amount of properdin factor B in serum and other body fluids is evidence of the involvement of the alternative to the classical pathway of activation of complement (a group of plasma proteins which cause the destruction of cells which are foreign to the body). Measurement of properdin factor B aids in the diagnosis of several kidney diseases, e.g., chronic glomerulonephritis (inflammation of the glomeruli of the kidney), lupus nephritis (kidney disease associated with a multisystem autoimmune disease, systemic lupus erythematosus), as well as several skin diseases, e.g., dermatitis herpetiformis (presence of vesicles on the skin that burn and itch), and pemphigus vulgaris (large vesicles on the skin). Other diseases in which the alternate pathway of complement activation has been implicated include rheumatoid arthritis, sickle cell anemia, and gram-negative bacteremia.

(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]

§ 866.5330 Factor XIII, A, S, immunological test system.

(a) **Identification.** A factor XIII, A, S, immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the factor XIII (a blood clotting factor), in platelets (A) or serum (S). Measurements of factor XIII, A, S, aid in the diagnosis and treatment of certain bleeding disorders resulting from a deficiency of this factor.

(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. This exemption does not apply to factor deficiency tests classified under §864.7290 of this chapter.

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

§ 866.5340 Ferritin immunological test system.

(a) **Identification.** A ferritin immunological test system is a device that consists of the reagents used to