§ 866.5800  
(b) Classification. Class II (special controls). The special control is FDA’s “Guidance for Industry and FDA Reviewers: Class II Special Control Guidance Document for Anti-Saccharomyces cerevisiae (S. cerevisiae) Antibody (ASCA) Premarket Notifications.”
[65 FR 70307, Nov. 22, 2000]

§ 866.5800 Seminal fluid (sperm) immunological test system.

(a) Identification. A seminal fluid (sperm) immunological test system is a device that consists of the reagents used for legal purposes to identify and differentiate animal and human semen. The test results may be used as court evidence in alleged instances of rape and other sex-related crimes.

(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 the limitations in § 866.9.

§ 866.5820 Systemic lupus erythematosus immunological test system.

(a) Identification. A systemic lupus erythematosus (SLE) immunological test system is a device that consists of the reagents used to measure by immunoochemical techniques the autoimmune antibodies in serum and other body fluids that react with cellular nuclear double-stranded deoxyribonucleic acid (DNA) or other nuclear constituents that are specifically diagnostic of SLE. Measurement of nuclear double-stranded DNA antibodies aids in the diagnosis of SLE (a multisystem autoimmune disease in which tissues are attacked by the person’s own antibodies).

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

§ 866.5880 Transferrin immunological test system.

(a) Identification. A transferrin immunological test system is a device that consists of the reagents used to measure by immunoochemical techniques the transferrin (an iron-binding and transporting serum protein) in serum, plasma, and other body fluids. Measurement of transferrin levels aids in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders, such as iron deficiency anemia.

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

§ 866.5890 Inter-alpha trypsin inhibitor immunological test system.

(a) Identification. An inter-alpha trypsin inhibitor immunological test system is a device that consists of the reagents used to measure by immunoochemical techniques the inter-alpha trypsin inhibitor (a protein) in serum and other body fluids. Measurement of inter-alpha trypsin inhibitor