(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-\textit{Saccharomyces cerevisiae} (\textit{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 immunochemoanalytical 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 immunochemoanalytical 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 immunochemoanalytical techniques the inter-alpha trypsin inhibitor (a protein) in serum and other body fluids. Measurement of inter-alpha trypsin inhibitor proteins may aid in the diagnosis of multiple sclerosis and other diseases of the nervous system.

(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.

may aid in the diagnosis of acute bacterial infection and inflammation.

(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.


§ 866.5900 Cystic fibrosis transmembrane conductance regulator (CFTR) gene mutation detection system.

(a) Identification. The CFTR gene mutation detection system is a device used to simultaneously detect and identify a panel of mutations and variants in the CFTR gene. It is intended as an aid in confirmatory diagnostic testing of individuals with suspected cystic fibrosis (CF), carrier identification, and newborn screening. This device is not intended for standalone diagnostic purposes, prenatal diagnostic, pre-implantation, or population screening.

(b) Classification. Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: CFTR Gene Mutation Detection System.” See §866.1(e) for the availability of this guidance document.

[70 FR 61738, Oct. 26, 2005]

§ 866.5910 Quality control material for cystic fibrosis nucleic acid assays.

(a) Identification. Quality control material for cystic fibrosis nucleic acid assays. A quality control material for cystic fibrosis nucleic acid assays is a device intended to help monitor reliability of a test system by detecting analytical deviations such as those that may arise from reagent or instrument variation in genetic testing. This type of device includes recombinant, synthetic, and cell line-based DNA controls.

(b) Classification. Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Quality Control Material for Cystic Fibrosis Nucleic Acid Assays.” See §866.1(e) for the availability of this guidance document.

[72 FR 1176, Jan. 10, 2007]

Subpart G—Tumor Associated Antigen immunological Test Systems

§ 866.6010 Tumor-associated antigen immunological test system.

(a) Identification. A tumor-associated antigen immunological test system is a device that consists of reagents used to qualitatively or quantitatively measure, by immunochromic techniques, tumor-associated antigens in serum, plasma, urine, or other body fluids. This device is intended as an aid in monitoring patients for disease progress or response to therapy or for the detection of recurrent or residual disease.

(b) Classification. Class II (special controls). Tumor markers must comply with the following special controls: (1) A guidance document entitled “Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications (510(k)s) to FDA,” and (2) voluntary assay performance standards issued by the National Committee on Clinical Laboratory Standards.


§ 866.6020 Immunomagnetic circulating cancer cell selection and enumeration system.

(a) Identification. An immunomagnetic circulating cancer cell selection and enumeration system is a device that consists of biological probes, fluorochromes, and other reagents; preservation and preparation devices; and a semiautomated analytical instrument to select and count circulating cancer cells in a prepared sample of whole blood. This device is intended for adjunctive use in monitoring or predicting cancer disease progression, response to therapy, and for the detection of recurrent disease.

(b) Classification. Class II (special controls). The special control for this device is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Immunomagnetic Circulating Cancer Cell Selection and