through gel which originally contains specific antibodies. As the reagents come in contact with each other, they combine to form a precipitate that is trapped in the gel matrix and immobilized.

(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.

[47 FR 50823, Nov. 9, 1982, as amended at 66 FR 38792, July 25, 2001]

§ 866.4830 Rocket immunoelectrophoresis equipment.

(a) **Identification.** Rocket immunoelectrophoresis equipment for clinical use is a device used to perform a specific test on proteins by using a procedure called rocket immunoelectrophoresis. In this procedure, an electric current causes the protein in solution to migrate through agar gel containing specific antiserum. The protein precipitates with the antiserum in a rocket-shaped pattern, giving the name to the device. The height of the peak (or the area under the peak) is proportional to the concentration of the 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 the limitations in §866.9.


§ 866.4900 Support gel.

(a) **Identification.** A support gel for clinical use is a device that consists of an agar or agarose preparation that is used while measuring various kinds of, or parts of, protein molecules by various immunochromatographic techniques, such as immunoelectrophoresis, immunodiffusion, or chromatography.

(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.


Subpart F—Immunological Test Systems

§ 866.5040 Albumin immunological test system.

(a) **Identification.** An albumin immunological test system is a device that consists of the reagents used to measure by immunochromatographic techniques the albumin (a plasma protein) in serum and other body fluids. Measurement of albumin aids in the diagnosis of kidney and intestinal diseases.

(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]

§ 866.5060 Prealbumin immunological test system.

(a) **Identification.** A prealbumin immunological test system is a device that consists of the reagents used to measure by immunochromatographic techniques the prealbumin (a plasma protein) in serum and other body fluids. Measurement of prealbumin levels in serum may aid in the assessment of the patient’s nutritional status.

(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]

§ 866.5065 Human allotypic marker immunological test system.

(a) **Identification.** A human allotypic marker immunological test system is a device that consists of the reagents used to identify by immunochromatographic techniques the inherited human protein allotypic markers (such as nGm, nA^2 m, and Km allotypes) in serum and other body fluids. The identification may be used while studying population genetics.

(b) **Classification.** Class I (general controls). The device is exempt from the premarket notification procedures in
§ 866.5080  Alpha-1-antichymotrypsin immunological test system.

(a) Identification. An alpha-1-antichymotrypsin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques alpha-1-antichymotrypsin (a protein) in serum, other body fluids, and tissues. Alpha-1-antichymotrypsin helps protect tissues against proteolytic (protein-splitting) enzymes released during infection.

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

§ 866.5090  Antimitochondrial antibody immunological test system.

(a) Identification. An antimitochondrial antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the antimitochondrial antibodies in human serum. The measurements aid in the diagnosis of diseases that produce a spectrum of autoantibodies (antibodies produced against the body’s own tissue), such as primary biliary cirrhosis (degeneration of liver tissue) and chronic active hepatitis (inflammation of the liver).

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

§ 866.5100  Antinuclear antibody immunological test system.

(a) Identification. An antinuclear antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoimmune antibodies in serum, other body fluids, and tissues that react with cellular nuclear constituents (molecules present in the nucleus of a cell, such as ribonucleic acid, deoxyribonucleic acid, or nuclear proteins). The measurements aid in the diagnosis of systemic lupus erythematosus (a multisystem autoimmune disease in which antibodies attack the victim’s own tissues), hepatitis (a liver disease), rheumatoid arthritis, Sjögren’s syndrome (arthritis with inflammation of the eye, eyelid, and salivary glands), and systemic sclerosis (chronic hardening and shrinking of many body tissues).

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

§ 866.5110  Antiparietal antibody immunological test system.

(a) Identification. An antiparietal antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the specific antibody for gastric parietal cells in serum and other body fluids. Gastric parietal cells are those cells located in the stomach that produce a protein that enables vitamin B₁₂ to be absorbed by the body. The measurements aid in the diagnosis of vitamin B₁₂ deficiency (or pernicious anemia), atrophic gastritis (inflammation of the stomach), and autoimmune connective tissue diseases (diseases resulting when the body produces antibodies against its own tissues).

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

§ 866.5120  Antismooth muscle antibody immunological test system.

(a) Identification. An antismooth muscle antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the antismooth muscle antibodies (antibodies to nonstriated, involuntary muscle) in serum. The measurements aid in the diagnosis of chronic hepatitis (inflammation of the liver) and autoimmune connective tissue diseases (diseases resulting from antibodies produced against the body’s own tissues).

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

§ 866.5130  Alpha-1-antitrypsin immunological test system.

(a) Identification. An alpha-1-antitrypsin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha-1-antitrypsin (a plasma protein) in serum, other body fluids, and tissues. The measurements aid in the diagnosis of several conditions including juvenile and adult cirrhosis of the liver. In addition, alpha-1-