Food and Drug Administration, HHS

§ 866.5040 Albumin immunological test system.

(a) Identification. An albumin immunological test system is a device that consists of the reagents used to perform 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 antisera. The protein precipitates with the antisera 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 immunochemical 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.