

§ 866.4600

scattering from antigen-antibody complexes. The concentration of these complexes may be measured by means of reflected light. A beam of light passed through a solution is scattered by the particles in suspension. The amount of light is detected by a photodetector, which converts light energy into electrical energy. The amount of electrical energy registers on a readout system such as a digital voltmeter or a recording chart. This electrical readout is called the light-scattering value and is used to measure the concentration of antigen-antibody complexes. This generic type of device includes devices with various kinds of light sources, such as laser equipment.

(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 54 FR 25047, June 12, 1989; 66 FR 38792, July 25, 2001]

§ 866.4600 Ouchterlony agar plate.

(a) *Identification.* An ouchterlony agar plate for clinical use is a device containing an agar gel used to examine antigen-antibody reactions. In immunodiffusion, antibodies and antigens migrate toward each other through gel which originally contained neither of these reagents. As the reagents come in contact with each other, they combine to form a precipitate that is trapped in the gel matrix and is 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 54 FR 25047, June 12, 1989; 66 FR 38792, July 25, 2001]

§ 866.4700 Automated fluorescence *in situ* hybridization (FISH) enumeration systems.

(a) *Identification.* An automated FISH enumeration system is a device that consists of an automated scanning microscope, image analysis system, and customized software applications for FISH assays. This device is intended for *in vitro* diagnostic use with FISH

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assays as an aid in the detection, counting and classification of cells based on recognition of cellular color, size, and shape, and in the detection and enumeration of FISH signals in interphase nuclei of formalin-fixed, paraffin-embedded human tissue specimens.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled "Class II Special Controls Guidance Document: Automated Fluorescence *in situ* Hybridization (FISH) Enumeration Systems." See § 866.1(e) for the availability of this guidance document.

[70 FR 14534, Mar. 23, 2005]

§ 866.4800 Radial immunodiffusion plate.

(a) *Identification.* A radial immunodiffusion plate for clinical use is a device that consists of a plastic plate to which agar gel containing antiserum is added. In radial immunodiffusion, antigens migrate 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 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.