

Food and Drug Administration, HHS

§ 862.2500

requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2309, Jan. 14, 2000]

§ 862.2300 Colorimeter, photometer, or spectrophotometer for clinical use.

(a) *Identification.* A colorimeter, a photometer, or a spectrophotometer for clinical use is an instrument intended to measure radiant energy emitted, transmitted, absorbed, or reflected under controlled conditions. The device may include a monochromator to produce light of a specific wavelength.

(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 § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2309, Jan. 14, 2000]

§ 862.2310 Clinical sample concentrator.

(a) *Identification.* A clinical sample concentrator is a device intended to concentrate (by dialysis, evaporation, etc.) serum, urine, cerebrospinal fluid, and other body fluids before the fluids are analyzed.

(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 § 862.9.

[52 FR 16122, May 1, 1987, as amended at 60 FR 38899, July 28, 1995; 66 FR 38788, July 25, 2001]

§ 862.2320 Beta or gamma counter for clinical use.

(a) *Identification.* A beta or gamma counter for clinical use is a device intended to detect and count beta or gamma radiation emitted by clinical samples. Clinical samples are prepared by addition of a radioactive reagent to the sample. These measurements are useful in the diagnosis and treatment of various disorders.

(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 § 862.9.

[52 FR 16122, May 1, 1987, as amended at 60 FR 38900, July 28, 1995; 66 FR 38788, July 25, 2001]

§ 862.2400 Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use.

(a) *Identification.* A densitometer/scanner (integrating, reflectance, thin-layer chromatography, or radiochromatogram) for clinical use is a device intended to measure the concentration of a substance on the surface of a film or other support media by either a photocell measurement of the light transmission through a given area of the medium or, in the case of the radiochromatogram scanner, by measurement of the distribution of a specific radio-active element on a radiochromatogram.

(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 § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2309, Jan. 14, 2000]

§ 862.2485 Electrophoresis apparatus for clinical use.

(a) *Identification.* An electrophoresis apparatus for clinical use is a device intended to separate molecules or particles, including plasma proteins, lipoproteins, enzymes, and hemoglobulins on the basis of their net charge in specified buffered media. This device is used in conjunction with certain materials to measure a variety of analytes as an aid in the diagnosis and treatment of certain disorders.

(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 § 862.9.

[52 FR 16122, May 1, 1987, as amended at 60 FR 38900, July 28, 1995; 66 FR 38788, July 25, 2001]

§ 862.2500 Enzyme analyzer for clinical use.

(a) *Identification.* An enzyme analyzer for clinical use is a device intended to measure enzymes in plasma or serum

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by nonkinetic or kinetic measurement of enzyme-catalyzed reactions. This device is used in conjunction with certain materials to measure a variety of enzymes as an aid in the diagnosis and treatment of certain enzyme-related disorders.

(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 § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2309, Jan. 14, 2000]

§ 862.2540 Flame emission photometer for clinical use.

(a) *Identification*. A flame emission photometer for clinical use is a device intended to measure the concentration of sodium, potassium, lithium, and other metal ions in body fluids. Abnormal variations in the concentration of these substances in the body are indicative of certain disorders (e.g., electrolyte imbalance and heavy metal intoxication) and are, therefore, useful in diagnosis and treatment of those disorders.

(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 § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2309, Jan. 14, 2000]

§ 862.2560 Fluorometer for clinical use.

(a) *Identification*. A fluorometer for clinical use is a device intended to measure by fluorescence certain analytes. Fluorescence is the property of certain substances of radiating, when illuminated, a light of a different wavelength. This device is used in conjunction with certain materials to measure a variety of analytes.

(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 § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2309, Jan. 14, 2000]

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§ 862.2570 Instrumentation for clinical multiplex test systems.

(a) *Identification*. Instrumentation for clinical multiplex test systems is a device intended to measure and sort multiple signals generated by an assay from a clinical sample. This instrumentation is used with a specific assay to measure multiple similar analytes that establish a single indicator to aid in diagnosis. Such instrumentation may be compatible with more than one specific assay. The device includes a signal reader unit, and may also integrate reagent handling, hybridization, washing, dedicated instrument control, and other hardware components, as well as raw data storage mechanisms, data acquisition software, and software to process detected signals.

(b) *Classification*. Class II (special controls). The special control is FDA's guidance document entitled "Class II Special Controls Guidance Document: Instrumentation for Clinical Multiplex Test Systems." See § 862.1(d) for the availability of this guidance document.

[70 FR 11868, Mar. 10, 2005]

§ 862.2680 Microtitrator for clinical use.

(a) *Identification*. A microtitrator for clinical use is a device intended for use in micronanalysis to measure the concentration of a substance by reacting it with a measure "micro" volume of a known standardized solution.

(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 § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2309, Jan. 14, 2000]

§ 862.2700 Nephelometer for clinical use.

(a) *Identification*. A nephelometer for clinical use is a device intended to estimate the concentration of particles in a suspension by measuring their light scattering properties (the deflection of light rays by opaque particles in their path). The device is used in conjunction with certain materials to measure the concentration of a variety of analytes.