

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