

Food and Drug Administration, HHS

§ 862.2320

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]

§ 862.2260 High pressure liquid chromatography system for clinical use.

(a) *Identification.* A high pressure liquid chromatography system for clinical use is a device intended to separate one or more drugs or compounds from a solution by processing the mixture of compounds (solutes) through a column packed with materials of uniform size (stationary phase) under the influence of a high pressure liquid (mobile phase). Separation of the solutes occurs either by absorption, sieving, partition, or selective affinity.

(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]

§ 862.2270 Thin-layer chromatography system for clinical use.

(a) *Identification.* A thin-layer chromatography (TLC) system for clinical use is a device intended to separate one or more drugs or compounds from a mixture. The mixture of compounds is absorbed onto a stationary phase or thin layer of inert material (e.g., cellulose, alumina, etc.) and eluted off by a moving solvent (moving phase) until equilibrium occurs between the two phases.

(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. Particular components of TLC systems, i.e., the thin-layer chromatography apparatus, TLC atomizer, TLC developing tanks, and TLC ultraviolet light, are exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to general 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