§ 862.2750 Pipetting and diluting system for clinical use.

(a) Identification. A pipetting and diluting system for clinical use is a device intended to provide an accurately measured volume of liquid at a specified temperature for use in certain test procedures. This generic type of device system includes serial, manual, automated, and semi-automated dilutors, pipettors, dispensers, and pipetting stations.

(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.


§ 862.2750 Mass spectrometer for clinical use.

(a) Identification. A mass spectrometer for clinical use is a device intended to identify inorganic or organic compounds (e.g., lead, mercury, and drugs) in human specimens by ionizing the compound under investigation and separating the resulting ions by means of an electrical and magnetic field according to their mass.

(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.


§ 862.2750 Atomic absorption spectrophotometer for clinical use.

(a) Identification. An atomic absorption spectrophotometer for clinical use is a device intended to identify and measure elements and metals (e.g., lead and mercury) in human specimens. The metal elements are identified according to the wavelength and intensity of the light that is absorbed when the specimen is converted to the atomic vapor phase. Measurements obtained by this device are used in the diagnosis and treatment of certain conditions.

(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.