§ 862.2860 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.

§ 862.2900 Automated urinalysis system.

(a) Identification. An automated urinalysis system is a device intended to measure certain of the physical properties and chemical constituents of urine by procedures that duplicate manual urinalysis systems. This device is used in conjunction with certain materials to measure a variety of urinary 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.

§ 862.2920 Plasma viscometer for clinical use.

(a) Identification. A plasma viscometer for clinical use is a device intended to measure the viscosity of plasma by determining the time period required for the plasma to flow a measured distance through a calibrated glass tube. Measurements obtained by this device are used to monitor changes in the amount of solids present in plasma in 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.