§ 862.2170 Micro chemistry analyzer for clinical use.

(a) Identification. A micro chemistry analyzer for clinical use is a device intended to duplicate manual analytical procedures by performing automatically various steps such as pipetting, preparing filtrates, heating, and measuring color intensity. The distinguishing characteristic of the device is that it requires only micro volume samples obtainable from pediatric patients. This device is intended for use 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 2308, Jan. 14, 2000]

§ 862.2230 Chromatographic separation material for clinical use.

(a) Identification. A chromatographic separation material for clinical use is a device accessory (e.g., ion exchange absorbents, ion exchange resins, and ion papers) intended for use in ion exchange chromatography, a procedure in which a compound is separated from a 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 the limitations in § 862.9.


§ 862.2250 Gas liquid chromatography system for clinical use.

(a) Identification. A gas liquid chromatography system for clinical use is a device intended to separate one or more drugs or compounds from a mixture. Each of the constituents in a vaporized mixture of compounds is separated according to its vapor pressure. The device may include accessories such as columns, gases, column supports, and liquid coating.

(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 2308, Jan. 14, 2000]