respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 16122, May 1, 1987, as amended at 66 FR 38788, July 25, 2001]

§ 862.2100 Calculator/data processing module for clinical use.

(a) *Identification.* A calculator/data processing module for clinical use is an electronic device intended to store, retrieve, and process laboratory data.

(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 53 FR 21449, June 8, 1988; 66 FR 38788, July 25, 2001]

§ 862.2140 Centrifugal chemistry analyzer for clinical use.

(a) *Identification.* A centrifugal chemistry analyzer for clinical use is an automatic device intended to centrifugally mix a sample and a reagent and spectrophotometrically measure concentrations of the sample constituents. 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]

§ 862.2150 Continuous flow sequential multiple chemistry analyzer for clinical use.

(a) *Identification.* A continuous flow sequential multiple chemistry analyzer for clinical use is a modular analytical instrument intended to simultaneously perform multiple chemical procedures using the principles of automated continuous flow systems. 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]

§ 862.2160 Discrete photometric chemistry analyzer for clinical use.

(a) *Identification.* A discrete photometric 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. This device is intended for use in conjunction with certain materials to measure a variety of analytes. Different models of the device incorporate various instrumentation such as micro analysis apparatus, double beam, single, or dual channel photometers, and bichromatic 2-wavelength photometers. Some models of the device may include reagent-containing components that may also serve as reaction units.

(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]

§ 862.2170 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 2309, Jan. 14, 2000]