(b) Classification. Class II (performance standards).

§ 864.8185 Calibrator for red cell and white cell counting.

(a) Identification. A calibrator for red cell and white cell counting is a device that resembles red or white blood cells and that is used to set instruments intended to count red cells, white cells, or both. It is a suspension of particles or cells whose size, shape, concentration, and other characteristics have been precisely and accurately determined.

(b) Classification. Class II (performance standards).

[45 FR 60633, Sept. 12, 1980]

§ 864.8200 Blood cell diluent.

(a) Identification. A blood cell diluent is a device used to dilute blood for further testing, such as blood cell counting.

(b) Classification. Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.


§ 864.8500 Lymphocyte separation medium.

(a) Identification. A lymphocyte separation medium is a device used to isolate lymphocytes from whole blood.

(b) Classification. Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.


§ 864.8540 Red cell lysing reagent.

(a) Identification. A red cell lysing reagent is a device used to lyse (destroy) red blood cells for hemoglobin determinations or aid in the counting of white blood cells.

(b) Classification. Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

[45 FR 60638, Sept. 12, 1980, as amended at 53 FR 11253, Apr. 6, 1988]