§ 864.8185  
(b) Classification. Class II (performance standards).
[45 FR 60633, Sept. 12, 1980]

§ 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 60634, 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.

Subpart J—Products Used In Establishments That Manufacture Blood and Blood Products

§ 864.8950 Russell viper venom reagent.
(a) Identification. Russell viper venom reagent is a device used to determine the cause of an increase in the prothrombin time.
(b) Classification. Class I (general controls).
[45 FR 60637, Sept. 12, 1980]