§ 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.


§ 864.8625 Hematology quality control mixture.

(a) **Identification.** A hematology quality control mixture is a device used to ascertain the accuracy and precision of manual, semiautomated, and automated determinations of cell parameters such as white cell count (WBC), red cell count (RBC), platelet count (PL/T), hemoglobin, hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC).

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

[45 FR 60638, Sept. 12, 1980]

§ 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]