§ 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 (PLT), 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 66373, 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 66373, Sept. 12, 1980]