Food and Drug Administration, HHS

§ 864.8175 Calibrator for platelet counting.

(a) Identification. A calibrator for platelet counting is a device that resembles platelets in plasma or whole blood and that is used to set a platelet counting instrument. 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]

§ 864.8185 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.


§ 864.8950 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]