

## Food and Drug Administration, HHS

§ 864.9100

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. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 60635, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989]

### § 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. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 60636, Sept. 12, 1980, as amended at 59 FR 63007, Dec. 7, 1994]

### § 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. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 60636, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989]

### § 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 60637, 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]

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

### § 864.9050 Blood bank supplies.

(a) *Identification*. Blood bank supplies are general purpose devices intended for in vitro use in blood banking. This generic type of device includes products such as blood bank pipettes, blood grouping slides, blood typing tubes, blood typing racks, and cold packs for antisera reagents. The device does not include articles that are licensed by the Center for Biologics Evaluation and Research of the Food and Drug Administration.

(b) *Classification*. Class I (general controls).

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

### § 864.9100 Empty container for the collection and processing of blood and blood components.

(a) *Identification*. An empty container for the collection and processing of blood and blood components is a device intended for medical purposes that is an empty plastic bag or plastic or glass bottle used to collect, store, or transfer blood and blood components for further processing.

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

[45 FR 60638, Sept. 12, 1980]