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been precisely and accurately determined.

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

[45 FR 60632, Sept. 12, 1980]

§ 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.

[45 FR 60635, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989; 66 FR 38790, July 25, 2001]

§ 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

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premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

[45 FR 60636, Sept. 12, 1980, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38790, July 25, 2001]

§ 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.

[45 FR 60636, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989; 66 FR 38790, July 25, 2001]

§ 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

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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]

§ 864.9125 Vacuum-assisted blood collection system.

(a) *Identification*. A vacuum-assisted blood collection system is a device intended for medical purposes that uses a vacuum to draw blood for subsequent reinfusion.

(b) *Classification*. Class I (general controls). The manual device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60639, Sept. 12, 1980, as amended at 65 FR 2310, Jan. 14, 2000]

§ 864.9145 Processing system for frozen blood.

(a) *Identification*. A processing system for frozen blood is a device used to glycerolize red blood cells prior to freezing to minimize hemolysis (disruption of the red cell membrane accompanied by the release of hemoglobin) due to freezing and thawing of red blood cells and to deglycerolize and wash thawed cells for subsequent reinfusion.

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

[45 FR 60639, Sept. 12, 1980]

§ 864.9160 Blood group substances of nonhuman origin for in vitro diagnostic use.

(a) *Identification*. Blood group substances of nonhuman origin for in vitro diagnostic use are materials, such as blood group specific substances prepared from nonhuman sources (e.g., pigs, cows, and horses) used to detect, identify, or neutralize antibodies to various human blood group antigens. This generic type of device does not include materials that are licensed by the Center for Biologics Evaluation and Research of the Food and Drug Administration.

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60640, Sept. 12, 1980, as amended at 53 FR 11253, Apr. 6, 1988; 63 FR 59225, Nov. 3, 1998]

§ 864.9175 Automated blood grouping and antibody test system.

(a) *Identification*. An automated blood grouping and antibody test system is a device used to group erythrocytes (red blood cells) and to detect antibodies to blood group antigens.

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

[45 FR 60641, Sept. 12, 1980]

§ 864.9185 Blood grouping view box.

(a) *Identification*. A blood grouping view box is a device with a glass or plastic viewing surface, which may be illuminated and heated, that is used to view cell reactions in antigen-antibody testing.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60641, Sept. 12, 1980, as amended at 65 FR 2310, Jan. 14, 2000]