

§ 864.1

- 864.7440 Electrophoretic hemoglobin analysis system.
- 864.7455 Fetal hemoglobin assay.
- 864.7470 Glycosylated hemoglobin assay.
- 864.7490 Sulfhemoglobin assay.
- 864.7500 Whole blood hemoglobin assays.
- 864.7525 Heparin assay.
- 864.7660 Leukocyte alkaline phosphatase test.
- 864.7675 Leukocyte peroxidase test.
- 864.7695 Platelet factor 4 radioimmunoassay.
- 864.7720 Prothrombin consumption test.
- 864.7735 Prothrombin-proconvertin test and thrombotest.
- 864.7750 Prothrombin time test.
- 864.7825 Sickle cell test.
- 864.7875 Thrombin time test.
- 864.7900 Thromboplastin generation test.
- 864.7925 Partial thromboplastin time tests.

Subpart I—Hematology Reagents

- 864.8100 Bothrops atrox reagent.
- 864.8150 Calibrator for cell indices.
- 864.8165 Calibrator for hemoglobin or hematocrit measurement.
- 864.8175 Calibrator for platelet counting.
- 864.8185 Calibrator for red cell and white cell counting.
- 864.8200 Blood cell diluent.
- 864.8500 Lymphocyte separation medium.
- 864.8540 Red cell lysing reagent.
- 864.8625 Hematology quality control mixture.
- 864.8950 Russell viper venom reagent.

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

- 864.9050 Blood bank supplies.
- 864.9100 Empty container for the collection and processing of blood and blood components.
- 864.9125 Vacuum-assisted blood collection system.
- 864.9145 Processing system for frozen blood.
- 864.9160 Blood group substances of nonhuman origin for in vitro diagnostic use.
- 864.9175 Automated blood grouping and antibody test system.
- 864.9185 Blood grouping view box.
- 864.9195 Blood mixing devices and blood weighing devices.
- 864.9205 Blood and plasma warming device.
- 864.9225 Cell-freezing apparatus and reagents for in vitro diagnostic use.
- 864.9245 Automated blood cell separator.
- 864.9275 Blood bank centrifuge for in vitro diagnostic use.
- 864.9285 Automated cell-washing centrifuge for immuno-hematology.
- 864.9300 Automated Coombs test systems.
- 864.9320 Copper sulfate solution for specific gravity determinations.

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- 864.9400 Stabilized enzyme solution.
- 864.9550 Lectins and protectins.
- 864.9575 Environmental chamber for storage of platelet concentrate.
- 864.9600 Potentiating media for in vitro diagnostic use.
- 864.9650 Quality control kit for blood banking reagents.
- 864.9700 Blood storage refrigerator and blood storage freezer.
- 864.9750 Heat-sealing device.
- 864.9875 Transfer set.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

Subpart A—General Provisions

§ 864.1 Scope.

(a) This part sets forth the classification of hematology and pathology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[52 FR 17732, May 11, 1987]

§ 864.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the