

this device are used in the diagnosis and treatment of chronic depression to ensure appropriate therapy.

(b) *Classification*. Class II.

§ 862.3950 Vancomycin test system.

(a) *Identification*. A vancomycin test system is a device intended to measure vancomycin, an antibiotic drug, in serum. Measurements obtained by this device are used in the diagnosis and treatment of vancomycin overdose and in monitoring the level of vancomycin to ensure appropriate therapy.

(b) *Classification*. Class II.

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

Subpart A—General Provisions

Sec.

- 864.1 Scope.
864.3 Effective dates of requirement for pre-market approval.
864.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Biological Stains

- 864.1850 Dye and chemical solution stains.
864.1860 Immunohistochemistry reagents and kits.

Subpart C—Cell and Tissue Culture Products

- 864.2220 Synthetic cell and tissue culture media and components.
864.2240 Cell and tissue culture supplies and equipment.
864.2260 Chromosome culture kit.
864.2280 Cultured animal and human cells.
864.2360 Mycoplasma detection media and components.
864.2800 Animal and human sera.
864.2875 Balanced salt solutions or formulations.

Subpart D—Pathology Instrumentation and Accessories

- 864.3010 Tissue processing equipment.
864.3250 Specimen transport and storage container.
864.3260 OTC test sample collection systems for drugs of abuse testing.
864.3300 Cytocentrifuge.
864.3400 Device for sealing microsections.
864.3600 Microscopes and accessories.
864.3800 Automated slide stainer.
864.3875 Automated tissue processor.

Subpart E—Specimen Preparation Reagents

- 864.4010 General purpose reagent.
864.4020 Analyte specific reagents.
864.4400 Enzyme preparations.

Subpart F—Automated and Semi-Automated Hematology Devices

- 864.5200 Automated cell counter.
864.5220 Automated differential cell counter.
864.5240 Automated blood cell diluting apparatus.
864.5260 Automated cell-locating device.
864.5300 Red cell indices device.
864.5350 Microsedimentation centrifuge.
864.5400 Coagulation instrument.
864.5425 Multipurpose system for in vitro coagulation studies.
864.5600 Automated hematocrit instrument.
864.5620 Automated hemoglobin system.
864.5680 Automated heparin analyzer.
864.5700 Automated platelet aggregation system.
864.5800 Automated sedimentation rate device.
864.5850 Automated slide spinner.
864.5950 Blood volume measuring device.

Subpart G—Manual Hematology Devices

- 864.6100 Bleeding time device.
864.6150 Capillary blood collection tube.
864.6160 Manual blood cell counting device.
864.6400 Hematocrit measuring device.
864.6550 Occult blood test.
864.6600 Osmotic fragility test.
864.6650 Platelet adhesion test.
864.6675 Platelet aggregometer.
864.6700 Erythrocyte sedimentation rate test.

Subpart H—Hematology Kits and Packages

- 864.7040 Adenosine triphosphate release assay.
864.7060 Antithrombin III assay.
864.7100 Red blood cell enzyme assay.
864.7140 Activated whole blood clotting time tests.
864.7250 Erythropoietin assay.
864.7275 Euglobulin lysis time tests.
864.7290 Factor deficiency test.
864.7300 Fibrin monomer paracoagulation test.
864.7320 Fibrinogen/fibrin degradation products assay.
864.7340 Fibrinogen determination system.
864.7360 Erythrocytic glucose-6-phosphate dehydrogenase assay.
864.7375 Glutathione reductase assay.
864.7400 Hemoglobin A₂ assay.
864.7415 Abnormal hemoglobin assay.
864.7425 Carboxyhemoglobin assay.