

§ 862.3900

theophylline (a drug used for stimulation of the muscles in the cardiovascular, respiratory, and central nervous systems) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of theophylline overdose or in monitoring levels of theophylline to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3900 **Tobramycin test system.**

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

(b) *Classification.* Class II.

§ 862.3910 **Tricyclic antidepressant drugs test system.**

(a) *Identification.* A tricyclic antidepressant drugs test system is a device intended to measure any of the tricyclic antidepressant drugs in serum. The tricyclic antidepressant drugs include imipramine, desipramine, amitriptyline, nortriptyline, protriptyline, and doxepin. Measurements obtained by 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.

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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.