§ 862.3950

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.
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.
864.2975 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.