Food and Drug Administration, HHS

§ 862.3870 Cannabinoid test system.
(a) Identification. A cannabinoid test system is a device intended to measure any of the cannabinoids, hallucinogenic compounds endogenous to marijuana, in serum, plasma, saliva, and urine. Cannabinoid compounds include delta-9-tetrahydrocannabinol, cannabinol, cannabidiol, and cannabichromene. Measurements obtained by this device are used in the diagnosis and treatment of cannabinoid use or abuse and in monitoring levels of cannabinoids during clinical investigational use.
(b) Classification. Class II.

§ 862.3880 Theophylline test system.
(a) Identification. A theophylline test system is a device intended to measure 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.