

Food and Drug Administration, HHS

§ 862.3910

are used in the diagnosis and treatment of propoxyphene use or overdose or in monitoring levels of propoxyphene to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3750 Quinine test system.

(a) *Identification.* A quinine test system is a device intended to measure quinine, a fever-reducing and pain-relieving drug intended in the treatment of malaria, in serum and urine. Measurements obtained by this device are used in the diagnosis and treatment of quinine overdose and malaria.

(b) *Classification.* Class I.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21450, June 8, 1988; 65 FR 2310, Jan. 14, 2000]

§ 862.3830 Salicylate test system.

(a) *Identification.* A salicylate test system is a device intended to measure salicylates, a class of analgesic, antipyretic and anti-inflammatory drugs that includes aspirin, in human specimens. Measurements obtained by this device are used in diagnosis and treatment of salicylate overdose and in monitoring salicylate levels to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3840 Sirolimus test system.

(a) *Identification.* A sirolimus test system is a device intended to quantitatively determine sirolimus concentrations in whole blood. Measurements are used as an aid in management of transplant patients receiving therapy with sirolimus.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled "Class II Special Controls Guidance Document: Sirolimus Test Systems." See § 862.1(d) for the availability of this guidance document.

[69 FR 58259, Sept. 30, 2004]

§ 862.3850 Sulfonamide test system.

(a) *Identification.* A sulfonamide test system is a device intended to measure sulfonamides, any of the antibacterial drugs derived from sulfanilamide, in human specimens. Measurements obtained by this device are used in the di-

agnosis and treatment of sulfonamide overdose and in monitoring sulfonamide levels to ensure appropriate therapy.

(b) *Classification.* Class I.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21450, June 8, 1988; 65 FR 2310, Jan. 14, 2000]

§ 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, cannabidiol, cannabinal, 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