Food and Drug Administration, HHS

§ 862.3630 Ethosuximide test system.

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

(b) Classification. Class II.

§ 862.3580 Lysergic acid diethylamide (LSD) test system.

(a) Identification. A lysergic acid diethylamide (LSD) test system is a device intended to measure lysergic acid diethylamide, a hallucinogenic drug, in serum, urine, and gastric contents. Measurements obtained by this device are used in the diagnosis and treatment of LSD overdose.

(b) Classification. Class II.

§ 862.3600 Mercury test system.

(a) Identification. A mercury test system is a device intended to measure mercury, a heavy metal, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of mercury poisoning.

(b) Classification. Class I.

§ 862.3610 Methamphetamine test system.

(a) Identification. A methamphetamine test system is a device intended to measure methamphetamine, a central nervous system stimulating drug, in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of methamphetamine overdose.

(b) Classification. Class II.

§ 862.3620 Methadone test system.

(a) Identification. A methadone test system is a device intended to measure methadone, an addictive narcotic pain-relieving drug, in serum and urine. Measurements obtained by this device are used in the diagnosis and treatment of methadone overdose and to determine compliance with regulations in methadone maintenance treatment.

(b) Classification. Class II.

§ 862.3630 Methaqualone test system.

(a) Identification. A methaqualone test system is a device intended to measure methaqualone, a hypnotic and sedative drug, in urine. Measurements obtained by this device are used in the diagnosis and treatment of methaqualone overdose.

(b) Classification. Class II.