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 human specimens. 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.

§ 862.3650 Gentamicin test system.
(a) Identification. A gentamicin test system is a device intended to measure gentamicin, an antibiotic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of gentamicin overdose and in monitoring levels of gentamicin to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3680 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 use or overdose.
(b) Classification. Class II.

§ 862.3690 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.

§ 862.3720 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 use or overdose.
(b) Classification. Class II.

§ 862.3750 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 use or overdose and to determine compliance with regulations in methadone maintenance treatment.
(b) Classification. Class II.

§ 862.3780 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 use or overdose.
(b) Classification. Class II.