

§ 862.3620

21 CFR Ch. I (4–1–10 Edition)

§ 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 use or 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 use or overdose.

(b) *Classification.* Class II.

§ 862.3640 Morphine test system.

(a) *Identification.* A morphine test system is a device intended to measure morphine, an addictive narcotic pain-relieving drug, and its analogs in serum, urine, and gastric contents. Measurements obtained by this device are used in the diagnosis and treatment of morphine use or overdose and in monitoring levels of morphine and its analogs to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3645 Neuroleptic drugs radioceptor assay test system.

(a) *Identification.* A neuroleptic drugs radioceptor assay test system is a device intended to measure in serum or plasma the dopamine receptor blocking activity of neuroleptic drugs and their active metabolites. A neuroleptic drug has anti-psychotic action affecting principally psychomotor activity, is generally without hypnotic effects, and is a tranquilizer. Measurements obtained by this device are used to aid in determining whether a patient is taking the prescribed dosage level of such drugs.

(b) *Classification.* Class II.

§ 862.3650 Opiate test system.

(a) *Identification.* An opiate test system is a device intended to measure

any of the addictive narcotic pain-relieving opiate drugs in blood, serum, urine, gastric contents, and saliva. An opiate is any natural or synthetic drug that has morphine-like pharmacological actions. The opiates include drugs such as morphine, morphine glucuronide, heroin, codeine, nalorphine, and meperidine. Measurements obtained by this device are used in the diagnosis and treatment of opiate use or overdose and in monitoring the levels of opiate administration to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3660 Phenobarbital test system.

(a) *Identification.* A phenobarbital test system is a device intended to measure phenobarbital, an antiepileptic and sedative-hypnotic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of phenobarbital use or overdose and in monitoring levels of phenobarbital to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3670 Phenothiazine test system.

(a) *Identification.* A phenothiazine test system is a device intended to measure any of the drugs of the phenothiazine class in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of phenothiazine use or overdose.

(b) *Classification.* Class II.

§ 862.3680 Primidone test system.

(a) *Identification.* A primidone test system is a device intended to measure primidone, an antiepileptic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of primidone overdose and in monitoring levels of primidone to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3700 Propoxyphene test system.

(a) *Identification.* A propoxyphene test system is a device intended to measure propoxyphene, a pain-relieving drug, in serum, plasma, and urine. Measurements obtained by this device