

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 glucoronide, heroin, codeine, nalorphine, and meperedine. 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 (special controls). An opiate test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (*e.g.*, programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

[52 FR 16122, May 1, 1987, as amended at 84 FR 71798, Dec. 30, 2019]

§ 862.3652 Organophosphate test system.

(a) *Identification*. An organophosphate test system is a device intended to measure organophosphate metabolites quantitatively in human urine from individuals who have signs and symptoms consistent with cholinesterase poisoning. The data obtained by this device is intended to aid in the con-

firmation and investigation of organophosphate exposure.

(b) *Classification*. Class II (special controls). The special controls for this device are:

(1) The distribution of these devices is limited to laboratories with experienced personnel who are trained to measure and evaluate organophosphate exposure and guide public health response.

(2) Analytical testing must demonstrate the device has appropriate performance characteristics, including adequate precision and accuracy across the measuring range and near medical decision points.

[82 FR 48415, Oct. 18, 2017]

§ 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