

chlorzepate, flurazepam, and nitrazepam. Measurements obtained by this device are used in the diagnosis and treatment of benzodiazepine use or overdose and in monitoring levels of benzodiazepines to ensure appropriate therapy.

(b) *Classification.* Class II.

§ 862.3200 Clinical toxicology calibrator.

(a) *Identification.* A clinical toxicology calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens. A clinical toxicology calibrator can be a mixture of drugs or a specific material for a particular drug (e.g., ethanol, lidocaine, etc.). (See also § 862.2 in this part.)

(b) *Classification.* Class II.

§ 862.3220 Carbon monoxide test system.

(a) *Identification.* A carbon monoxide test system is a device intended to measure carbon monoxide or carboxyhemoglobin (carbon monoxide bound to the hemoglobin in the blood) in blood. Measurements obtained by this device are used in the diagnosis and treatment of or confirmation of carbon monoxide poisoning.

(b) *Classification.* Class I.

§ 862.3240 Cholinesterase test system.

(a) *Identification.* A cholinesterase test system is a device intended to measure cholinesterase (an enzyme that catalyzes the hydrolysis of acetylcholine to choline) in human specimens. There are two principal types of cholinesterase in human tissues. True cholinesterase is present at nerve endings and in erythrocytes (red blood cells) but is not present in plasma. Pseudo cholinesterase is present in plasma and liver but is not present in erythrocytes. Measurements obtained by this device are used in the diagnosis and treatment of cholinesterase inhibition disorders (e.g., insecticide poisoning and succinylcholine poisoning).

(b) *Classification.* Class I.

§ 862.3250 Cocaine and cocaine metabolite test system.

(a) *Identification.* A cocaine and cocaine metabolite test system is a device intended to measure cocaine and a cocaine metabolite (benzoylecgonine) in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of cocaine use or overdose.

(b) *Classification.* Class II.

§ 862.3270 Codeine test system.

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

(b) *Classification.* Class II.

§ 862.3280 Clinical toxicology control material.

(a) *Identification.* A clinical toxicology control material is a device intended to provide an estimation of the precision of a device test system and to detect and monitor systematic deviations from accuracy resulting from reagent or instrument defects. This generic type of device includes various single, and multi-analyte control materials.

(b) *Classification.* Class I (general controls). Except when used in donor screening, unassayed material is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2309, Jan. 14, 2000]

§ 862.3300 Digitoxin test system.

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

(b) *Classification.* Class II.