Food and Drug Administration, HHS

§ 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 arsenic poisoning.

(b) Classification. Class I.

§ 862.3150 Barbiturate test system.

(a) Identification. A barbiturate test system is a device intended to measure barbiturates, a class of hypnotic and sedative drugs, in serum, urine, and gastric contents. Measurements obtained by this device are used in the diagnosis and treatment of barbiturate use or overdose and in monitoring levels of barbiturates to ensure appropriate therapy.

(b) Classification. Class II.

§ 862.3170 Benzodiazepine test system.

(a) Identification. A benzodiazepine test system is a device intended to measure any of the benzodiazepine compounds, sedative and hypnotic drugs, in blood, plasma, and urine. The benzodiazepine compounds include chlor Diazepoxide, diazepam, oxazepam, clorazepate, 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