

§ 862.3300

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.

§ 862.3320 Digoxin test system.

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

(b) *Classification*. Class II.

§ 862.3350 Diphenylhydantoin test system.

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

(b) *Classification*. Class II.

§ 862.3360 Drug metabolizing enzyme genotyping system.

(a) *Identification*. A drug metabolizing enzyme genotyping system is a device intended for use in testing deoxyribonucleic acid (DNA) extracted from clinical samples to identify the presence or absence of human genotypic markers encoding a drug metabolizing enzyme. This device is used as an aid in determining treatment

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choice and individualizing treatment dose for therapeutics that are metabolized primarily by the specific enzyme about which the system provides genotypic information.

(b) *Classification*. Class II (special controls). The special control is FDA's guidance document entitled "Class II Special Controls Guidance Document: Drug Metabolizing Enzyme Genotyping Test System." See § 862.1(d) for the availability of this guidance document.

[70 FR 11867, Mar. 10, 2005]

§ 862.3380 Ethosuximide test system.

(a) *Identification*. An ethosuximide test system is a device intended to measure ethosuximide, an antiepileptic 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.

§ 862.3450 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.

§ 862.3520 Kanamycin test system.

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

(b) *Classification*. Class II.

§ 862.3550 Lead test system.

(a) *Identification*. A lead test system is a device intended to measure lead, a heavy metal, in blood and urine. Measurements obtained by this device are used in the diagnosis and treatment of lead poisoning.

(b) *Classification*. Class II.