§ 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 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.

§ 862.3555 Lidocaine test system.

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

(b) *Classification.* Class II.

§ 862.3560 Lithium test system.

(a) *Identification.* A lithium test system is a device intended to measure lithium (from the drug lithium carbonate) in serum or plasma. Measurements of lithium are used to assure that the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).

(b) *Classification.* Class II.

§ 862.3580 Lysergic acid diethylamide (LSD) test system.

(a) *Identification.* A lysergic acid diethylamide (LSD) test system is a device intended to measure lysergic acid diethylamide, a hallucinogenic drug, in serum, urine, and gastric contents. Measurements obtained by this device are used in the diagnosis and treatment of LSD use or overdose.

(b) *Classification.* Class II (special controls). A lysergic acid diethylamide (LSD) 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