choice and individualizing treatment
dose for therapeutics that are metabo-
lized 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. Measure-
ments obtained by this device are used
in the diagnosis and treatment of ethosuximide overdose and in moni-
toring 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 ob-
tained by this device are used in the di-
agnosis and treatment of gentamicin
overdose and in monitoring levels of
genamicin to ensure appropriate ther-
apy.

(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 plas-
ma 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. Measure-
ments 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 sys-
tem is a device intended to measure
lidocaine, an antiarrhythmic and
anticonvulsant drug, in serum and
plasma. Measurements obtained by this
device are used in the diagnosis and
monitoring levels of lidocaine to en-
sure appropriate therapy.

(b) **Classification.** Class II.

§ 862.3560 Lithium test system.

(a) **Identification.** A lithium test sys-
tem is a device intended to measure
lithium (from the drug lithium car-
bonate) in serum or plasma. Measure-
ments of lithium are used to assure
that the proper drug dosage is adminis-
tered in the treatment of patients with
mental disturbances, such as manic-de-
pressive 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 con-
tents. Measurements obtained by this
device are used in the diagnosis and
monitoring levels of LSD use or overdose.

(b) **Classification.** Class II.

§ 862.3600 Mercury test system.

(a) **Identification.** A mercury test sys-
tem is a device intended to measure
mercury, a heavy metal, in human
specimens. Measurements obtained by
this device are used in the diagnosis and
monitoring levels of mercury poisoning.

(b) **Classification.** Class I.

§ 862.3610 Methamphetamine test sys-
tem.

(a) **Identification.** A methamphet-
amine test system is a device intended
to measure methamphetamine, a cen-
tral nervous system stimulating drug,
in serum, plasma, and urine. Measure-
ments obtained by this device are used
in the diagnosis and treatment of
methamphetamine use or overdose.

(b) **Classification.** Class II.