§ 862.3870  
overdose and in monitoring sulfa-
fonamide levels to ensure appropriate
therapy.
(b) Classification. Class I.
[52 FR 16122, May 1, 1987, as amended at 53
FR 21450, June 8, 1988; 65 FR 2310, Jan. 14,
2000]

§ 862.3870 Cannabinoid test system.
(a) Identification. A cannabinoid test
system is a device intended to measure
any of the cannabinoids, hallucino-
genic compounds endogenous to mari-
huana, in serum, plasma, saliva, and
urine. Cannabinoid compounds include
delta-9-tetrahydrocannabinol,
cannabidiol, cannabinol, and
cannabinomene. Measurements ob-
tained by this device are used in the di-
agnosis and treatment of cannabinoid
use or abuse and in monitoring levels
of cannabinoids during clinical inves-
tigational use.
(b) Classification. Class II.

§ 862.3880 Theophylline test system.
(a) Identification. A theophylline test
system is a device intended to measure
theophylline (a drug used for stimula-
tion of the muscles in the cardio-
vascular, respiratory, and central nerv-
ous systems) in serum and plasma.
Measurements obtained by this device
are used in the diagnosis and treat-
ment of theophylline overdose or in
monitoring levels of theophylline to
ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3900 Tobramycin test system.
(a) Identification. A tobramycin test
system is a device intended to measure

tobramycin, an aminoglycoside anti-
biotic drug, in plasma and serum.
Measurements obtained by this device
are used in the diagnosis and treat-
ment of tobramycin overdose and in
monitoring levels of tobramycin to en-
sure appropriate therapy.
(b) Classification. Class II.

§ 862.3910 Tricyclic antidepressant
drugs test system.
(a) Identification. A tricyclic anti-
depressant drugs test system is a device
intended to measure any of the
tricyclic antidepressant drugs in
serum. The tricyclic antidepressant
drugs include imipramine,
desipramine, amitriptyline,
nortriptyline, protriptyline, and
doxepin. Measurements obtained by
this device are used in the diagnosis
and treatment of chronic depression to
ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3950 Vancomycin test system.
(a) Identification. A vancomycin test
system is a device intended to measure
vancomycin, an antibiotic drug, in
serum. Measurements obtained by this
device are used in the diagnosis and
monitoring of the level of vancomycin
to ensure appropriate therapy.
(b) Classification. Class II.

PART 864—HEMATOLOGY AND
PATHOLOGY DEVICES
Subpart A—General Provisions
Sec.
864.1 Scope.
864.3 Effective dates of requirement for pre-
market approval.
864.9 Limitations of exemptions from sec-
tion 510(k) of the Federal Food, Drug,
and Cosmetic Act (the act).

Subpart B—Biological Stains
864.1850 Dye and chemical solution stains.
864.1860 Immunohistochemistry reagents
and kits.

Subpart C—Cell and Tissue Culture
Products
864.2220 Synthetic cell and tissue culture
media and components.
864.2240 Cell and tissue culture supplies and
equipment.
864.2250 Chromosome culture kit.
864.2280 Cultured animal and human cells.
864.2360 Mycoplasma detection media and
components.
864.2800 Animal and human sera.
864.2875 Balanced salt solutions or formula-
tions.

Subpart D—Pathology Instrumentation and
Accessories
864.3010 Tissue processing equipment.
864.3250 Specimen transport and storage
container.
864.3290 OTC test sample collection systems
for drugs of abuse testing.
864.3300 Cytocentrifuge.
864.3400 Device for sealing microsections.
864.3600 Microscopes and accessories.