§ 864.7040
for the red cells in a blood sample to
fall a specified distance or a device
that measures the degree of sedimenta-
tion taking place in a given length of
time. An increased rate indicates tis-
sue damage or inflammation.
(b) Classification. Class I (general con-
trols). This device is exempt from the
premarket notification procedures in
subpart E of part 807 of this chapter
subject to the limitations in §864.9.
[45 FR 60608, Sept. 12, 1980, as amended at 54
FR 25045, June 12, 1989; 66 FR 38790, July 25,
2001]

Subpart H—Hematology Kits and
Packages
§ 864.7040 Adenosine triphosphate re-
lease assay.
(a) Identification. An adenosine
triphosphate release assay is a device
that measures the release of adenosine
triphosphate (ATP) from platelets fol-
lowing aggregation. This measurement
is made on platelet-rich plasma using a
photometer and a luminescent firefly
extract. Simultaneous measurements
of platelet aggregation and ATP re-
lease are used to evaluate platelet
function disorders.
(b) Classification. Class I (general
controls).
[45 FR 60609, Sept. 12, 1980]

§ 864.7060 Antithrombin III assay.
(a) Identification. An antithrombin
III assay is a device used to deter-
mine the plasma level of antithrombin
III (a substance which acts with the
anticoagulant heparin to prevent co-
agulation). This determination is used
to monitor the administration of heparin
in the treatment of thrombosis.
The determination may also be used in
the diagnosis of thrombophilia (a con-
genital deficiency of antithrombin III).
(b) Classification. Class II (perform-
ance standards).
[45 FR 60610, Sept. 12, 1980]

§ 864.7100 Red blood cell enzyme
assay.
(a) Identification. Red blood cell en-
zyme assay is a device used to measure
the activity in red blood cells of clinic-
ally important enzymatic reactions
and their products, such as pyruvate
kinase or 2,3-diphosphoglycerate. A red
blood cell enzyme assay is used to de-
termine the enzyme defects responsible
for a patient’s hereditary hemolytic
anemia.
(b) Classification. Class II (perform-
ance standards).
[45 FR 60610, Sept. 12, 1980]

§ 864.7140 Activated whole blood clot-
ting time tests.
(a) Identification. An activated whole
blood clotting time tests is a device,
used to monitor heparin therapy for
the treatment of venous thrombosis or
pulmonary embolism by measuring the
coagulation time of whole blood.
(b) Classification. Class II (perform-
ance standards).
[45 FR 60611, Sept. 12, 1980]

§ 864.7250 Erythropoietin assay.
(a) Identification. An erythropoietin
assay is a device that measures the
concentration of erythropoietin (an en-
zyme that regulates the production of
red blood cells) in serum or urine. This
assay provides diagnostic information
for the evaluation of erythrocytosis
(increased total red cell mass) and ane-
mia.
(b) Classification. Class II. The special
control for this device is FDA’s “Docu-
ment for Special Controls for Erythro-
poietin Assay Premarket Notification
(510(k)s).”
[45 FR 60612, Sept. 12, 1980, as amended at 52
FR 17733, May 11, 1987; 65 FR 17144, Mar. 31,
2000]

§ 864.7275 Euglobulin lysis time tests.
(a) Identification. A euglobulin lysis
time test is a device that measures the
length of time required for the lysis
(dissolution) of a clot formed from fibrinogen in the euglobulin
fraction (that fraction of the plasma responsible
for the formation of plasmin, a clot
lysing enzyme). This test evaluates
natural fibrinolysis (destruction of a
blood clot after bleeding has been ar-
rested). The test also will detect accel-
erated fibrinolysis.
(b) Classification. Class II (perform-
ance standards).
[45 FR 60612, Sept. 12, 1980]