red cell volume of a blood sample to distinguish normal from abnormal states, such as anemia and erythrocytosis (an increase in the number of red cells).

(b) Classification. Class II (performance standards).

§ 864.5620 Automated hemoglobin system.

(a) Identification. An automated hemoglobin system is a fully automated or semi-automated device which may or may not be part of a larger system. The generic type of device consists of the reagents, calibrators, controls, and instrumentation used to determine the hemoglobin content of human blood.

(b) Classification. Class II (performance standards).

§ 864.5680 Automated heparin analyzer.

(a) Identification. An automated heparin analyzer is a device used to determine the heparin level in a blood sample by mixing the sample with protamine (a heparin-neutralizing substance) and determining photometrically the onset of air-activated clotting. The analyzer also determines the amount of protamine necessary to neutralize the heparin in the patient’s circulation.

(b) Classification. Class II (special controls).

§ 864.5700 Automated platelet aggregation system.

(a) Identification. An automated platelet aggregation system is a device used to determine changes in platelet shape and platelet aggregation following the addition of an aggregating reagent to a platelet-rich plasma.

(b) Classification. Class II (performance standards).

§ 864.5800 Automated sedimentation rate device.

(a) Identification. An automated sedimentation rate device is an instrument that measures automatically the erythrocyte sedimentation rate in whole blood. Because an increased sedimentation rate indicates tissue damage or inflammation, the erythrocyte sedimentation rate device is useful in monitoring treatment of a disease.

(b) Classification. Class I (general controls). 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.

§ 864.5850 Automated slide spinner.

(a) Identification. An automated slide spinner is a device that prepares automatically a blood film on a microscope slide using a small amount of peripheral blood (blood circulating in one of the body’s extremities, such as the arm).

(b) Classification. Class I (general controls). 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.

§ 864.5950 Blood volume measuring device.

(a) Identification. A blood volume measuring device is a manual, semi-automated, or automated system that is used to calculate the red cell mass, plasma volume, and total blood volume.

(b) Classification. Class II (performance standards).

Subpart G—Manual Hematology Devices

§ 864.6100 Bleeding time device.

(a) Identification. A bleeding time device is a device, usually employing two spring-loaded blades, that produces two small incisions in the patient’s skin. The length of time required for the bleeding to stop is a measure of the effectiveness of the coagulation system, primarily the platelets.
(b) **Classification.** Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §864.9.


§ 864.6150 Capillary blood collection tube.

(a) **Identification.** A capillary blood collection tube is a plain or heparinized glass tube of very small diameter used to collect blood by capillary action.

(b) **Classification.** Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §864.9.


§ 864.6160 Manual blood cell counting device.

(a) **Identification.** A manual blood cell counting device is a device used to count red blood cells, white blood cells, or blood platelets.

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


§ 864.6400 Hematocrit measuring device.

(a) **Identification.** A hematocrit measuring device is a system consisting of instruments, tubes, racks, and a sealer and a holder. The device is used to measure the packed red cell volume in blood to determine whether the patient’s total red cell volume is normal or abnormal. Abnormal states include anemia (an abnormally low total red cell volume) and erythrocytosis (an abnormally high total red cell mass). The packed red cell volume is produced by centrifuging a given volume of blood.

(b) **Classification.** Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §864.9.


§ 864.6550 Occult blood test.

(a) **Identification.** An occult blood test is a device used to detect occult blood in urine or feces. (Occult blood is blood present in such small quantities that it can be detected only by chemical tests of suspected material, or by microscopic or spectroscopic examination.)

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

[45 FR 60606, Sept. 12, 1980]

§ 864.6600 Osmotic fragility test.

(a) **Identification.** An osmotic fragility test is a device used to determine the resistance of red blood cells to hemolysis (destruction) in varying concentrations of hypotonic saline solutions.

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


§ 864.6650 Platelet adhesion test.

(a) **Identification.** A platelet adhesion test is a device used to determine in vitro platelet function.

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

[45 FR 60608, Sept. 12, 1980]

§ 864.6675 Platelet aggregometer.

(a) **Identification.** A platelet aggregometer is a device, used to determine changes in platelet shape and platelet aggregation following the addition of an aggregating reagent to a platelet rich plasma.

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

[45 FR 60608, Sept. 12, 1980]

§ 864.6700 Erythrocyte sedimentation rate test.

(a) **Identification.** An erythrocyte sedimentation rate test is a device that measures the length of time required
for the red cells in a blood sample toall 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 3870, 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 that is 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 cli-
cially 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.** A 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 17114, 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]