§ 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.

§ 864.6600 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).

§ 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).

§ 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 fall a specified distance or a device that measures the degree of sedimentation taking place in a given length of time. An increased rate indicates tissue damage or inflammation.

(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.


Subpart H—Hematology Kits and Packages

§864.7040 Adenosine triphosphate release assay.

(a) Identification. An adenosine triphosphate release assay is a device that measures the release of adenosine triphosphate (ATP) from platelets following aggregation. This measurement is made on platelet-rich plasma using a photometer and a luminescent firefly extract. Simultaneous measurements of platelet aggregation and ATP release 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 determine the plasma level of antithrombin III (a substance which acts with the anticoagulant heparin to prevent coagulation). 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 congenital deficiency of antithrombin III).

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

[45 FR 60610, Sept. 12, 1980]

§864.7100 Red blood cell enzyme assay.

(a) Identification. Red blood cell enzyme assay is a device used to measure the activity in red blood cells of clinically important enzymatic reactions and their products, such as pyruvate kinase or 2,3-diphosphoglycerate. A red blood cell enzyme assay is used to determine the enzyme defects responsible for a patient’s hereditary hemolytic anemia.

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

[45 FR 66610, Sept. 12, 1980]

§864.7250 Erythropoietin assay.

(a) Identification. A erythropoietin assay is a device that measures the concentration of erythropoietin (an enzyme 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 anemia.

(b) Classification. Class II. The special control for this device is FDA’s ‘‘Document for Special Controls for Erythropoietin Assay Premarket Notification (510(k)s).’’


§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 arrested). The test also will detect accelerated fibrinolysis.

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

[45 FR 66612, Sept. 12, 1980]