§ 864.5800  
(b) **Classification.** Class II (performance standards).

[45 FR 60602, Sept. 12, 1980]

§ 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).

[45 FR 60603, Sept. 12, 1980]

§ 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 administration of an aggregating reagent to a platelet rich plasma.

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

[45 FR 60608, Sept. 12, 1980]

§ 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).