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 (performance standards).

§ 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.

§ 864.5950 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).

§ 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.