

## § 864.5620

erythrocytosis (an increase in the number of red cells).

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

[45 FR 60600, Sept. 12, 1980]

## § 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).

[45 FR 60601, Sept. 12, 1980]

## § 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).

[45 FR 60601, Sept. 12, 1980, as amended at 52 FR 17733, May 11, 1987; 58 FR 51571, Oct. 4, 1993]

## § 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).

[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 sedi-

## 21 CFR Ch. I (4-1-01 Edition)

mentation rate indicates tissue damage or inflammation, the erythrocyte sedimentation rate device is useful in monitoring treatment of a disease.

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

[45 FR 60602, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989]

## § 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. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 60603, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989]

## § 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]

## 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.

[45 FR 60604, Sept. 12, 1980, as amended at 63 FR 59225, Nov. 3, 1998]