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

(b) **Classification.** Class II (perform-
ance standards).

[45 FR 60660, Sept. 12, 1980]

§ 864.5620 **Automated hemoglobin sys-
tem.**

(a) **Identification.** An automated he-
moglobin 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 (perform-
ance standards).

[45 FR 60660, Sept. 12, 1980]

§ 864.5680 **Automated heparin ana-
lyzer.**

(a) **Identification.** An automated he-
parin analyzer is a device used to deter-
mine the heparin level in a blood sam-
ple by mixing the sample with prot-
amine (a heparin-neutralizing sub-
stance) and determining
photometrically the onset of air-acti-
vated clotting. The analyzer also deter-
mines the amount of protamine nec-
essary to neutralize the heparin in the
patient’s circulation.

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

[45 FR 60661, Sept. 12, 1980]

§ 864.5700 **Automated platelet aggrega-
tion system.**

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

(b) **Classification.** Class II (perform-
ance standards).

[45 FR 60662, Sept. 12, 1980]

§ 864.5800 **Automated sedimentation
rate device.**

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

(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 60662, Sept. 12, 1980, as amended at 54
FR 25045, June 12, 1989; 66 FR 38790, July 25,
2001]

§ 864.5850 **Automated slide spinner.**

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

(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 60663, Sept. 12, 1980, as amended at 54
FR 25045, June 12, 1989; 66 FR 38790, July 25,
2001]

§ 864.5950 **Blood volume measuring de-
vice.**

(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 vol-
ume.

(b) **Classification.** Class II (perform-
ance standards).

[45 FR 60663, Sept. 12, 1980]

**Subpart G—Manual Hematology
Devices**

§ 864.6100 **Bleeding time device.**

(a) **Identification.** A bleeding time de-
vice 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 ef-
fectiveness of the coagulation system,
primarily the platelets.
§ 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 60606, 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