§ 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]

§ 864.6700  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.