§ 864.5425 Multipurpose system for in vitro coagulation studies.

(a) Identification. A multipurpose system for in vitro coagulation studies is a device consisting of one automated or semiautomated instrument and its associated reagents and controls. The system is used to perform a series of coagulation studies and coagulation factor assays.

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

[45 FR 60599, Sept. 12, 1980]

§ 864.5600 Automated hematocrit instrument.

(a) Identification. An automated hematocrit instrument is a fully automated or semi-automated device which may or may not be part of a larger system. This device measures the packed 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).

[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]

§ 864.5800 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.