§ 864.7695 Platelet factor 4 radioimmunoassay.

(a) Identification. A platelet factor 4 radioimmunoassay is a device used to measure the level of platelet factor 4, a protein released during platelet activation by radioimmunoassay. This device measures platelet activation, which may indicate a coagulation disorder, such as myocardial infarction or coronary artery 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.


§ 864.7720 Prothrombin consumption test.

(a) Identification. A prothrombin consumption test is a device that measures the patient’s capacity to generate thromboplastin in the coagulation process. The test also is an indirect indicator of qualitative or quantitative platelet abnormalities. It is a screening test for thrombocytopenia (decreased number of blood platelets) and hemophilia A and B.

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


§ 864.7735 Prothrombin-proconvertin test and thrombotest.

(a) Identification. The prothrombin-proconvertin test and thrombotest are devices used in the regulation of coumarin therapy (administration of a coumarin anticoagulant such as sodium warfarin in the treatment of venous thrombosis and pulmonary embolism) and as a diagnostic test in conjunction with, or in place of, the Quick prothrombin time test to detect coagulation disorders.

(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.