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

[45 FR 60622, Sept. 12, 1980]

§ 864.7525 Heparin assay.

(a) *Identification*. A heparin assay is a device used to determine the level of the anticoagulant heparin in the patient's circulation. These assays are quantitative clotting time procedures using the effect of heparin on activated coagulation factor X (Stuart factor) or procedures based on the neutralization of heparin by protamine sulfate (a protein that neutralizes heparin).

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

[45 FR 60623, Sept. 12, 1980]

§ 864.7660 Leukocyte alkaline phosphatase test.

(a) *Identification*. A leukocyte alkaline phosphatase test is a device used to identify the enzyme leukocyte alkaline phosphatase in neutrophilic granulocytes (granular leukocytes stainable by neutral dyes). The cytochemical identification of alkaline phosphatase depends on the formation of blue granules in cells containing alkaline phosphatase. The results of this test are used to differentiate chronic granulocytic leukemia (a malignant disease characterized by excessive overgrowth of granulocytes in the bone marrow) and reactions that resemble true leukemia, such as those occuring in severe infections and polycythemia (increased total red cell mass).

(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.

[45 FR 60623, Sept. 12, 1980, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38790, July 25, 2001]

§ 864.7675 Leukocyte peroxidase test.

(a) *Identification*. A leukocyte peroxidase test is a device used to distinguish certain myeloid cells derived from the bone marrow, i.e., neutrophils, eosinophils, and monocytes, from lymphoid cells of the lymphatic system and erythroid cells of the red blood cell series on the basis of their peroxidase activity as evidenced by staining. The results of this test are used in the differential diagnosis of the leukemias.

(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.

[45 FR 60624, Sept. 12, 1980, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38790, July 25, 2001]

§ 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 activiation, which may indicate a coagulation disorder, such as myocardial infarction or coronary artery disease.

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

[45 FR 60625, Sept. 12, 1980; 46 FR 14890, Mar. 3, 1981]

§ 864.7720 Prothrombin consumption test.

(a) *Identification*. A prothrombin consumption tests 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).

[45 FR 60625, Sept. 12, 1980]

§ 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 II (performance standards).

[45 FR 60626, Sept. 12, 1980]

§ 864.7750 Prothrombin time test.

(a) *Identification.* A prothrombin time test is a device used as a general screening procedure for the detection of possible clotting factor deficiencies in the extrinsic coagulation pathway, which involves the reaction between coagulation factors III and VII, and to monitor patients receiving coumarin therapy (the administration of one of the coumarin anticoagulants in the treatment of venous thrombosis or pulmonary embolism).

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

[45 FR 60626, Sept. 12, 1980]

§ 864.7825 Sickle cell test.

(a) *Identification.* A sickle cell test is a device used to determine the sickle cell hemoglobin content of human blood to detect sickle cell trait or sickle cell diseases.

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

[45 FR 60627, Sept. 12, 1980]

§ 864.7875 Thrombin time test.

(a) *Identification.* A thrombin time test is a device used to measure fibrinogen concentration and detect fibrin or fibrinogen split products for the evaluation of bleeding disorders.

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

[45 FR 60628, Sept. 12, 1980]

§ 864.7900 Thromboplastin generation test.

(a) *Identification.* A thromboplastin generation test is a device used to detect and identify coagulation factor deficiencies and coagulation inhibitors.

(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.

[45 FR 60628, Sept. 12, 1980, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38790, July 25, 2001]

§ 864.7925 Partial thromboplastin time tests.

(a) *Identification.* A partial thromboplastin time test is a device used for primary screening for coagulation abnormalities, for evaluation of the effect of therapy on procoagulant disorders, and as an assay for coagulation factor deficiencies of the intrinsic coagulation pathway.

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

[45 FR 60629, Sept. 12, 1980]

Subpart I—Hematology Reagents

§ 864.8100 Bothrops atrox reagent.

(a) *Identification.* A Bothrops atrox reagent is a device made from snake venom and used to determine blood fibrinogen levels to aid in the evaluation of disseminated intravascular coagulation (nonlocalized clotting in the blood vessels) in patients receiving heparin therapy (the administration of the anticoagulant heparin in the treatment of thrombosis) or as an aid in the classification of dysfibrinogenemia (presence in the plasma of functionally defective fibrinogen).

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

[45 FR 60629, Sept. 12, 1980]

§ 864.8150 Calibrator for cell indices.

(a) *Identification.* A calibrator for cell indices is a device that approximates whole blood or certain blood cells and that is used to set an instrument intended to measure mean cell volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC), or other cell indices. It is a suspension of particles or cells whose size, shape, concentration, and other characteristics have been precisely and accurately determined.

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

[45 FR 60631, Sept. 12, 1980]

§ 864.8165 Calibrator for hemoglobin or hematocrit measurement.

(a) *Identification.* A calibrator for hemoglobin or hematocrit measurement is a device that approximates whole