fibrinolysis (dissolution of the fibrin in a blood clot).

(b) *Classification.* Class II. The special control for this device is FDA's ''In Vitro Diagnostic Fibrin Monomer Paracoagulation Test.''

[45 FR 60614, Sept. 12, 1980, as amended at 52 FR 17733, May 11, 1987; 65 FR 17144, Mar. 31, 2000]

§ 864.7320 Fibrinogen/fibrin degradation products assay.

(a) *Identification.* A fibrinogen/fibrin degradation products assay is a device used to detect and measure fibrinogen degradation products and fibrin degradation products (protein fragments produced by the enzymatic action of plasmin on fibrinogen and fibrin) as an aid in detecting the presence and degree of intravascular coagulation and fibrinolysis (the dissolution of the fibrin in a blood clot) and in monitoring therapy for disseminated intravascular coagulation (nonlocalized clotting in the blood vessels).

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

[45 FR 60615, Sept. 12, 1980]

§ 864.7340 Fibrinogen determination system.

(a) *Identification.* A fibrinogen determination system is a device that consists of the instruments, reagents, standards, and controls used to determine the fibrinogen levels in disseminated intravascular coagulation (nonlocalized clotting within the blood vessels) and primary fibrinolysis (the dissolution of fibrin in a blood clot).

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

[45 FR 60615, Sept. 12, 1980]

§ 864.7360 Erythrocytic glucose-6-phosphate dehydrogenase assay.

(a) *Identification.* An erythrocytic glucose-6-phosphate dehydrogenase assay is a device used to measure the activity of the enzyme glucose-6-phosphate dehydrogenase or of glucose-6-phosphate dehydrogenase isoenzymes. The results of this assay are used in the diagnosis and treatment of nonspherocytic congenital hemolytic anemia or drug-induced hemolytic anemia associated with a glucose-6-phosphate dehydrogenase deficiency. This generic device includes assays based on fluorescence, electrophoresis, methemoglobin reduction, catalase inhibition, and ultraviolet kinetics.

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

[45 FR 60616, Sept. 12, 1980]

§ 864.7375 Glutathione reductase assay.

(a) *Identification.* A glutathione reductase assay is a device used to determine the activity of the enzyme glutathione reductase in serum, plasma, or erythrocytes by such techniques as fluorescence and photometry. The results of this assay are used in the diagnosis of liver disease, glutathione reductase deficiency, or riboflavin deficiency.

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

[45 FR 60616, Sept. 12, 1980]

§ 864.7400 Hemoglobin A_2 assay.

(a) *Identification.* A hemoglobin A_2 assay is a device used to determine the hemoglobin A_2 content of human blood. The measurement of hemoglobin A_2 is used in the diagnosis of the thalassemias (hereditary hemolytic anemias characterized by decreased synthesis of one or more types of hemoglobin polypeptide chains).

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

[45 FR 60617, Sept. 12, 1980]

§ 864.7415 Abnormal hemoglobin assay.

(a) *Identification.* An abnormal hemoglobin assay is a device consisting of the reagents, apparatus, instrumentation, and controls necessary to isolate and identify abnormal genetically determined hemoglobin types.

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

[45 FR 60618, Sept. 12, 1980]

§ 864.7425 Carboxyhemoglobin assay.

(a) *Identification.* A carboxyhemoglobin assay is a device used to determine the carboxyhemoglobin (the compound formed when hemoglobin is exposed to carbon monoxide) content of human