

§ 866.5420 Alpha-1-glycoproteins immunological test system.

(a) *Identification.* An *alpha-1-glycoproteins immunological test system* is a device that consists of the reagents used to measure by immunochemical techniques *alpha-1-glycoproteins* (a group of plasma proteins found in the *alpha-1* group when subjected to electrophoresis) in serum and other body fluids. Measurement of specific *alpha-1-glycoproteins* may aid in the diagnosis of collagen (connective tissue) disorders, tuberculosis, infections, extensive malignancy, and diabetes.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2312, Jan. 14, 2000]

§ 866.5425 Alpha-2-glycoproteins immunological test system.

(a) *Identification.* An *alpha-2-glycoproteins immunological test system* is a device that consists of the reagents used to measure by immunochemical techniques the *alpha-2-glycoproteins* (a group of plasma proteins found in the *alpha-2* group when subjected to electrophoresis) in serum and other body fluids. Measurement of *alpha-2-glycoproteins* aids in the diagnosis of some cancers and genetically inherited deficiencies of these plasma proteins.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2312, Jan. 14, 2000]

§ 866.5430 Beta-2-glycoprotein I immunological test system.

(a) *Identification.* A *beta-2-glycoprotein I immunological test system* is a device that consists of the reagents used to measure by immunochemical techniques the *beta-2-glycoprotein I* (a serum protein) in serum and other body fluids. Measurement of *beta-2-glycoprotein I* aids in

the diagnosis of an inherited deficiency of this serum protein.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2312, Jan. 14, 2000]

§ 866.5440 Beta-2-glycoprotein III immunological test system.

(a) *Identification.* A *beta-2-glycoprotein III immunological test system* is a device that consists of the reagents used to measure by immunochemical techniques the *beta-2-glycoprotein III* (a serum protein) in serum and other body fluids. Measurement of *beta-2-glycoprotein III* aids in the diagnosis of an inherited deficiency of this serum protein and a variety of other conditions.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2312, Jan. 14, 2000]

§ 866.5460 Haptoglobin immunological test system.

(a) *Identification.* A *haptoglobin immunological test system* is a device that consists of the reagents used to measure by immunochemical techniques the *haptoglobin* (a protein that binds hemoglobin, the oxygen-carrying pigment in red blood cells) in serum. Measurement of *haptoglobin* may aid in the diagnosis of hemolytic diseases (diseases in which the red blood cells rupture and release hemoglobin) related to the formation of hemoglobin-haptoglobin complexes and certain kidney diseases.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 63 FR 59227, Nov. 3, 1998]