Food and Drug Administration, HHS

§ 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]