§ 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 immunochromatographic 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]