§ 866.5735 Prothrombin immunological test system.

(a) Identification. A prothrombin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the prothrombin (clotting factor II) in serum. Measurements of the amount of antigenically competent (ability to react with protein antibodies) prothrombin aid in the diagnosis of blood-clotting disorders.

(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. This exemption does not apply to multipurpose systems for in vitro coagulation studies classified under §864.5425 of this chapter or prothrombin time tests classified under §864.7750 of this chapter.