Food and Drug Administration, HHS

§ 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 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.