Food and Drug Administration, HHS

§ 866.5060  Prealbumin immunological test system.

(a) Identification. A prealbumin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the prealbumin (a plasma protein) in serum and other body fluids. Measurement of prealbumin aids in the assessment of the patient’s nutritional status.

(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 the limitations in §866.9.