Food and Drug Administration, HHS

§ 866.5360 Cohn fraction IV immunological test system.

(a) Identification. A Cohn fraction IV immunological test system is a device that consists of or measures that fraction of plasma proteins, predominantly alpha- and beta-globulins, used as a raw material for the production of pure alpha- or beta-globulins. Measurement of specific alpha- or beta-globulins aids in the diagnosis of many diseases, such as Wilson’s disease (an inherited disease affecting the liver and brain), Tangier’s disease (absence of alpha-I-lipoprotein), malnutrition, iron deficiency anemia, red blood cell disorders, and kidney disease.

(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.