Food and Drug Administration, HHS

§ 862.1180 Chymotrypsin test system.

(a) Identification. A chymotrypsin test system is a device intended to measure the activity of the enzyme chymotrypsin in blood and other body fluids and in feces. Chymotrypsin measurements are used in the diagnosis and treatment of pancreatic exocrine insufficiency.

(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 §862.9.


§ 862.1185 Compound S (11-deoxycortisol) test system.

(a) Identification. A compound S (11-deoxycortisol) test system is a device intended to measure the level of compound S (11-deoxycortisol) in plasma. Compound S is a steroid intermediate in the biosynthesis of the adrenal hormone cortisol. Measurements of compound S are used in the diagnosis and treatment of certain adrenal and pituitary gland disorders resulting in clinical symptoms of masculinization and hypertension.

(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 §862.9.