§ 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.