Food and Drug Administration, HHS

§ 862.1515 Nitrogen (amino-nitrogen) test system.

(a) Identification. A nitrogen (amino-nitrogen) test system is a device intended to measure amino acid nitrogen levels in serum, plasma, and urine. Nitrogen (amino-nitrogen) measurements are used in the diagnosis and treatment of certain forms of severe liver disease and renal 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 the limitations in §862.9.