Food and Drug Administration, HHS

§ 862.1670 Sorbitol dehydrogenase test system.

(a) Identification. A sorbitol dehydrogenase test system is a device intended to measure the activity of the enzyme sorbitol dehydrogenase in serum. Measurements obtained by this device are used in the diagnosis and treatment of liver disorders such as cirrhosis or acute hepatitis.

(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.