Food and Drug Administration, HHS

§ 862.3520 Kanamycin test system.
(a) Identification. A kanamycin test system is a device intended to measure kanamycin, an antibiotic drug, in plasma and serum. Measurements obtained by this device are used in the diagnosis and treatment of kanamycin overdose and in monitoring levels of kanamycin to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3550 Lead test system.
(a) Identification. A lead test system is a device intended to measure lead, a heavy metal, in blood and urine. Measurements obtained by this device are used in the diagnosis and treatment of lead poisoning.
(b) Classification. Class II.