Food and Drug Administration, HHS

§ 862.1500 Malic dehydrogenase test system.
(a) Identification. A malic dehydrogenase test system is a device intended to measure the activity of the enzyme malic dehydrogenase in serum and plasma. Malic dehydrogenase measurements are used in the diagnosis and treatment of muscle and liver diseases, myocardial infarctions, cancer, and blood disorders such as myelogenous (produced in the bone marrow) leukemia.

(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.


§ 862.1505 Mucopolysaccharides (nonquantitative) test system.
(a) Identification. A mucopolysaccharides (nonquantitative) test system is a device intended to measure the levels of mucopolysaccharides in urine. Mucopolysaccharide measurements in urine are used in the diagnosis and treatment of various inherited disorders that affect bone and connective tissues, such as Hunter’s, Sanfilippo’s, Scheie’s Morquio’s and Maroteaux-Lamy syndromes.

(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.