§ 862.1377 Urinary homocystine (non-quantitative) test system.

(a) Identification. A urinary homocystine (nonquantitative) test system is a device intended to identify homocystine (an analogue of the amino acid cystine) in urine. The identification of urinary homocystine is used in the diagnosis and treatment of homocystinuria (homosystine in urine), a heritable metabolic disorder which may cause mental retardation.

(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.


§ 862.1380 Hydroxybutyric dehydrogenase test system.

(a) Identification. A hydroxybutyric dehydrogenase test system is a device intended to measure the activity of the enzyme alpha-hydroxybutyric dehydrogenase (HBD) in plasma or serum. HBD measurements are used in the diagnosis and treatment of myocardial infarction, renal damage (such as rejection of transplants), certain hematological diseases (such as acute leukemias and megaloblastic anemias) and, to a lesser degree, liver disease.

(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.


§ 862.1385 17-Hydroxyprogesterone (17-ketogenic steroids) test system.

(a) Identification. A 17-hydroxyprogesterone (17-ketogenic steroids) test system is a device intended to measure 17-hydroxyprogesterone (a steroid) in plasma and serum. Measurements of 17-hydroxyprogesterone are used in the diagnosis and treatment of various disorders of the adrenal glands or the ovaries.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in