§ 862.1810 Vitamin B_{12} test system.

(a) *Identification.* A vitamin B_{12} test system is a device intended to measure vitamin B_{12} in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.

(b) *Classification.* Class II.

§ 862.1815 Vitamin E test system.

(a) *Identification.* A vitamin E test system is a device intended to measure vitamin E (tocopherol) in serum. Measurements obtained by this device are used in the diagnosis and treatment of infants with vitamin E deficiency syndrome.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 subject to the limitations in § 862.9.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988; 66 FR 38788, July 25, 2001]

§ 862.1820 Xylose test system.

(a) *Identification.* A xylose test system is a device intended to measure xylose (a sugar) in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of gastrointestinal malabsorption syndrome (a group of disorders in which there is subnormal absorption of dietary constituents and thus excessive loss from the body of the nonabsorbed substances).

(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.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2308, Jan. 14, 2000]

§ 862.1825 Vitamin D test system.

(a) *Identification.* A vitamin D test system is a device intended for use in clinical laboratories for the quantitative determination of 25-hydroxyvitamin D (25-OH-D) and other hydroxylated metabolites of vitamin D in serum or plasma to be used in the assessment of vitamin D sufficiency.

(b) *Classification.* Class II (special controls). Vitamin D test systems must comply with the following special controls:

(1) Labeling in conformance with 21 CFR 809.10 and

(2) Compliance with existing standards of the National Committee on Clinical Laboratory Standards.

[63 FR 40366, July 29, 1998]

§ 862.1840 Total 25-hydroxyvitamin D mass spectrometry test system.

(a) *Identification.* A total 25-hydroxyvitamin D mass spectrometry test system is a device intended for use in clinical laboratories for the quantitative determination of total 25-hydroxyvitamin D (25–OH–D) in serum or plasma to be used in the assessment of vitamin D sufficiency.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in part 807, subpart E, of this chapter subject to the limitations in § 862.9. The device must comply with the following special controls:

(1) The device must have initial and annual standardization verification by a certifying vitamin D standardization organization deemed acceptable by FDA.

(2) The 21 CFR 809.10(b) compliant labeling must include detailed descriptions of performance testing conducted to evaluate precision, accuracy, linearity, interference, including the following:

(i) Performance testing of device precision must, at a minimum, use intended sample type with Vitamin D concentrations at medically relevant decision points. At least one sample in the precision studies must be an unmodified patient sample. This testing must evaluate repeatability and reproducibility using a protocol from an FDA-recognized standard.

(ii) Performance testing of device accuracy must include a minimum of 115 serum or plasma samples that span the measuring interval of the device and compare results of the new device to results of a reference method or a legally marketed standardized mass spectrometry based vitamin D assay. The results must be described in the 21 CFR 809.10(b)(12) compliant labeling of the device.