§ 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 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 809.19 and

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

[83 FR 40966, July 29, 1998]