a device intended to measure the activity of the enzyme galactose-1-phosphate uridyl transferase in erythrocytes (red blood cells). Measurements of galactose-1-phosphate uridyl transferase are used in the diagnosis and treatment of the hereditary disease galactosemia (disorder of galactose metabolism) in infants.

(b) *Classification.* Class II.

§ 862.1320 Gastric acidity test system.

(a) *Identification.* A gastric acidity test system is a device intended to measure the acidity of gastric fluid. Measurements of gastric acidity are used in the diagnosis and treatment of patients with peptic ulcer, Zollinger-Ellison syndrome (peptic ulcer due to gastrin-secreting tumor of the pancreas), and related gastric disorders.

(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.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988; 66 FR 38787, July 25, 2001]

§ 862.1325 Gastrin test system.

(a) *Identification.* A gastrin test system is a device intended to measure the hormone gastrin in plasma and serum. Measurements of gastrin are used in the diagnosis and treatment of patients with ulcers, pernicious anemia, and the Zollinger-Ellison syndrome (peptic ulcer due to a gastrin-secreting tumor of the pancreas).

(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 2306, Jan. 14, 2000]

§ 862.1330 Globulin test system.

(a) *Identification.* A globulin test system is a device intended to measure globulins (proteins) in plasma and serum. Measurements of globulin are used in the diagnosis and treatment of patients with numerous illnesses including severe liver and renal disease, multiple myeloma, and other disorders of blood globulins.

(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 2306, Jan. 14, 2000]

§ 862.1335 Glucagon test system.

(a) *Identification.* A glucagon test system is a device intended to measure the pancreatic hormone glucagon in plasma and serum. Glucagon measurements are used in the diagnosis and treatment of patients with various disorders of carbohydrate metabolism, including diabetes mellitus, hypoglycemia, and hyperglycemia.

(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 2306, Jan. 14, 2000]

§ 862.1340 Urinary glucose (nonquantitative) test system.

(a) *Identification.* A urinary glucose (nonquantitative) test system is a device intended to measure glucosuria (glucose in urine). Urinary glucose (nonquantitative) measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, hypoglycemia, and hyperglycemia.

(b) *Classification.* Class II.

§ 862.1345 Glucose test system.

(a) *Identification.* A glucose test system is a device intended to measure glucose quantitatively in blood and other body fluids. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

(b) *Classification.* Class II (special controls). The device, when it is solely

intended for use as a drink to test glucose tolerance, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

[52 FR 16122, May 1, 1987, as amended at 84 FR 71796, Dec. 30, 2019; 85 FR 18445, Apr. 2, 2020]

§ 862.1350 Continuous glucose monitor secondary alarm system.

(a) *Identification.* A continuous glucose monitor (CGM) secondary alarm system is identified as a device intended to be used as a secondary alarm for a CGM to enable immediate awareness for potential clinical intervention to help assure patient safety.

(b) *Classification.* Class II (special 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. The special controls for this device are:

(1) Devices being marketed must include appropriate measures to protect against unauthorized access to data and unauthorized modification of data.

(2) The labeling must prominently and conspicuously display a warning that states ''Dosing decisions should not be made based on this device. The user should follow instructions on the continuous glucose monitoring system.''

(3) The labeling for the device must include a statement that reads ''This device is not intended to replace self-monitoring practices as advised by a physician.''

[82 FR 13550, Mar. 14, 2017, as amended at 84 FR 71796, Dec. 30, 2019; 86 FR 20283, Apr. 19, 2021]

§ 862.1355 Integrated continuous glucose monitoring system.

(a) *Identification.* An integrated continuous glucose monitoring system (iCGM) is intended to automatically measure glucose in bodily fluids continuously or frequently for a specified period of time. iCGM systems are designed to reliably and securely transmit glucose measurement data to digitally connected devices, including automated insulin dosing systems, and are intended to be used alone or in conjunction with these digitally connected medical devices for the purpose of managing a disease or condition related to glycemic control.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Design verification and validation must include the following:

(i) Robust clinical data demonstrating the accuracy of the device in the intended use population.

(ii) The clinical data must include a comparison between iCGM values and blood glucose values in specimens collected in parallel that are measured on an FDA-accepted laboratory-based glucose measurement method that is precise and accurate, and that is traceable to a higher order (*e.g.*, an internationally recognized reference material and/or method).

(iii) The clinical data must be obtained from a clinical study designed to fully represent the performance of the device throughout the intended use population and throughout the measuring range of the device.

(iv) Clinical study results must demonstrate consistent analytical and clinical performance throughout the sensor wear period.

(v) Clinical study results in the adult population must meet the following performance requirements:

(A) For all iCGM measurements less than 70 milligrams/deciliter (mg/dL), the percentage of iCGM measurements within ±15 mg/dL of the corresponding blood glucose value must be calculated, and the lower one-sided 95 percent confidence bound must exceed 85 percent.

(B) For all iCGM measurements from 70 mg/dL to 180 mg/dL, the percentage of iCGM measurements within ±15 percent of the corresponding blood glucose value must be calculated, and the lower one-sided 95 percent confidence bound must exceed 70 percent.

(C) For all iCGM measurements greater than 180 mg/dL, the percentage of iCGM measurements within ±15 percent of the corresponding blood glucose value must be calculated, and the lower one-sided 95 percent confidence bound must exceed 80 percent.

(D) For all iCGM measurements less than 70 mg/dL, the percentage of iCGM measurements within ±40 mg/dL of the corresponding blood glucose value must be calculated, and the lower one-