§ 862.3030 Acetaminophen test system.
(a) Identification. An acetaminophen test system is a device intended to measure acetaminophen, an analgesic and fever reducing drug, in serum. Measurements obtained by this device are used in the diagnosis and treatment of acetaminophen overdose.

(b) Classification. Class II.

§ 862.3035 Amikacin test system.
(a) Identification. An amikacin test system is a device intended to measure amikacin, an aminoglycoside antibiotic drug, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of amikacin overdose and in monitoring levels of amikacin to ensure appropriate therapy.

(b) Classification. Class II.

§ 862.3040 Alcohol test system.
(a) Identification. An alcohol test system is a device intended to measure alcohol (e.g., ethanol, methanol, isopropanol, etc.) in human body fluids (e.g., serum, whole blood, and urine). Measurements obtained by this device are used in the diagnosis and treatment of alcohol intoxication and poisoning.

(b) Classification. Class II.

§ 862.3050 Breath-alcohol test system.
(a) Identification. A breath-alcohol test system is a device intended to measure alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.

(b) Classification. Class I.