§ 864.7440 Electrolyte analysis system.
(a) Identification. An electrolyte analysis system is a device designed to measure electrolyte concentrations in body fluids or tissues. Examples include sodium, potassium, chloride, bicarbonate, blood urea nitrogen, and creatinine.
(b) Classification. Class II (performance standards).
[45 FR 60619, Sept. 12, 1980]

§ 864.7450 Fetal hemoglobin assay.
(a) Identification. A fetal hemoglobin assay is a device used to measure the percentage of fetal hemoglobin (HbF) in a patient’s blood. This is often used in the diagnosis of certain hematological diseases such as sickle cell disease and thalassemia.
(b) Classification. Class II (performance standards).
[45 FR 60620, Sept. 12, 1980]

§ 864.7460 Glycosylated hemoglobin assay.
(a) Identification. A glycosylated hemoglobin assay is a device used to measure glycosylated hemoglobin (HbA1c) levels in a patient’s blood. These levels are indicative of the patient’s average blood glucose levels over the past 2-3 months, providing valuable information for diabetes management.
(b) Classification. Class II (performance standards).
[45 FR 60621, Sept. 12, 1980]