Food and Drug Administration, HHS

§ 866.5065 Subpart F—Immunological Test Systems

§ 866.5040 Albumin immunological test system.

(a) Identification. An albumin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the albumin (a plasma protein) in serum and other body fluids. Measurement of albumin aids in the diagnosis of kidney and intestinal diseases.

(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 § 866.9.

§ 866.5060 Prealbumin immunological test system.

(a) Identification. A prealbumin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the prealbumin (a plasma protein) in serum and other body fluids. Measurement of prealbumin levels in serum may aid in the assessment of the patient’s nutritional status.

(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 § 866.9.

§ 866.5065 Human allotypic marker immunological test system.

(a) Identification. A human allotypic marker immunological test system is a device that consists of the reagents used to identify by immunochemical techniques the inherited human protein allotypic markers (such as nGm, nA2m, and Km allotypes) in serum and other body fluids. The identification may be used while studying population genetics.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in