measurement of these proteins aids in the diagnosis of any disease concerned with abnormal levels of IgG gamma globulins such as agammaglobulinemia or multiple myeloma.

(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 § 866.9.


§ 866.5230 Colostrum immunological test system.

(a) Identification. A colostrum immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the specific proteins in colostrum. Colostrum is a substance excreted by the mammary glands during pregnancy and until production of breast milk begins 1 to 5 days after childbirth.

(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 § 866.9.


§ 866.5240 Complement components immunological test system.

(a) Identification. A complement components immunological test system is a device that consists of the reagents used to measure by immunochemical techniques complement components C1q, C1r, C1s, C2, C3, C4, C5, C6, C7, C8, and C9, in serum, other body fluids, and tissues. Complement is a group of serum proteins which destroy infectious agents. Measurements of these proteins aids in the diagnosis of immunologic disorders, especially those associated with deficiencies of complement components.

(b) Classification. Class II (performance standards).

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