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through gel which originally contained neither of these reagents. As the reagents come in contact with each other, they combine to form a precipitate that is trapped in the gel matrix and is immobilized.

(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.

[47 FR 50823, Nov. 9, 1982, as amended at 66 FR 38792, July 25, 2001]

§ 866.5040 **Albumin immunological test system.**

(a) **Identification.** An albumin immunological test system is a device that consists of the reagents used to

premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 66 FR 38792, July 25, 2001]