type of disease. Cryptococcosis infections are found most often as chronic meningitis (inflammation of brain membranes) and, if not treated, are usually fatal.

(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.


§ 866.3205 Echovirus serological reagents.

(a) **Identification.** Echovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to echovirus in serum. Additionally, some of these reagents consist of echovirus antisera conjugated with a fluorescent dye used to identify echoviruses from clinical specimens or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of echovirus infections and provides epidemiological information on diseases caused by these viruses. Echoviruses cause illnesses such as meningitis (inflammation of the brain and spinal cord membranes), febrile illnesses (accompanied by fever) with or without rash, and the common cold.

(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 54 FR 25046, June 12, 1989; 66 FR 38791, July 25, 2001]

§ 866.3210 Endotoxin assay.

(a) **Identification.** An endotoxin assay is a device that uses serological techniques in whole blood. The device is intended for use in conjunction with other laboratory findings and clinical assessment of the patient to aid in the risk assessment of critically ill patients for progression to severe sepsis.

(b) **Classification.** Class II (special controls). The special control for this device is the FDA guidance entitled “Class II Special Controls Guidance Document: Endotoxin Assay.” See §866.1(e) for the availability of this guidance document.