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(principally cytomegalic inclusion disease) and provides epidemiological information on these diseases. Cytomegalic inclusion disease is a generalized infection of infants and is caused by intrauterine or early postnatal infection with the virus. The disease may cause severe congenital abnormalities, such as microcephaly (abnormal smallness of the head), motor disability, and mental retardation. Cytomegalovirus infection has also been associated with acquired hemolytic anemia, acute and chronic hepatitis, and an infectious mononucleosis-like syndrome.

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

§ 866.3200 *Echinococcus* spp. serological reagents.

(a) *Identification. Echinococcus* spp. serological reagents are devices that consist of *Echinococcus* spp. antigens and antisera used in serological tests to identify antibodies to *Echinococcus* spp. in serum. The identification aids in the diagnosis of echinococcosis, caused by parasitic tapeworms belonging to the genus *Echinococcus* and provides epidemiological information on this disease. Echinococcosis is characterized by the development of cysts in the liver, lung, kidneys, and other organs formed by the larva of the infecting organisms.

(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.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2311, Jan. 14, 2000]

§ 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.

[68 FR 62008, Oct. 31, 2003. Redesignated at 70 FR 53069, Sept. 7, 2005]

§ 866.3220 *Entamoeba histolytica* serological reagents.

(a) *Identification. Entamoeba histolytica* serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Entamoeba histolytica* in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Entamoeba histolytica* directly from clinical specimens. The identification aids in the diagnosis of amebiasis caused by the microscopic protozoan parasite *Entamoeba histolytica* and provides epidemiological information on diseases caused by this parasite. The parasite may invade the skin, liver, intestines, lungs, and diaphragm, causing disease conditions such as indolent ulcers, an amebic hepatitis, amebic dysentery, and pulmonary lesions.