§ 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 larvae 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 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.


§ 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.