mild fever-producing illnesses to severe liver and kidney involvement producing hemorrhage and dysfunction of these organs.

(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.

[47 FR 50823, Nov. 9, 1982, as amended at 63 FR 59227, Nov. 3, 1998]

§ 866.3355 Listeria spp. serological reagents.

(a) Identification. Listeria spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify Listeria spp. from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of Listeria spp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify Listeria spp. directly from clinical specimens. The identification aids in the diagnosis of listeriosis, a disease caused by bacteria belonging to the genus Listeria, and provides epidemiological information on diseases caused by these microorganisms. Listeria monocytogenes, the most common human pathogen of this genus, causes meningitis (inflammation of the brain membranes) and meningoencephalitis (inflammation of the brain and brain membranes) and is often fatal if untreated. A second form of human listeriosis is an intrauterine infection in pregnant women that results in a high mortality rate for infants before or after birth.

(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.


§ 866.3370 Mycobacterium tuberculosis immunofluorescent reagents.

(a) Identification. Mycobacterium tuberculosis immunofluorescent reagents are devices that consist of antisera conjugated with a fluorescent dye used to identify Mycobacterium tuberculosis directly from clinical specimens. The identification aids in the diagnosis of tuberculosis and provides epidemiological information on this disease. Mycobacterium tuberculosis is the common causative organism in human tuberculosis, a chronic infectious disease characterized by formation of tubercles (small rounded nodules) and tissue necrosis (destruction), usually occurring in the lung.

(b) Classification. Class I (general controls).

§ 866.3375 Mycoplasma spp. serological reagents.

(a) Identification. Mycoplasma spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Mycoplasma spp. in serum. Additionally, some of these reagents consist of Mycoplasma spp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify Mycoplasma spp. directly from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus Mycoplasma and provides epidemiological information on diseases caused by these microorganisms. Mycoplasma spp.