§ 866.3355

L. monocytogenes, the most common human pathogen of this genus, causes meningoencephalitis and meningitis. L. monocytogenes is the most common human pathogen of this genus, causing 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 **Mycoplasma spp. serological reagents.**

(a) **Identification.** Mycoplasma spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify 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 these microorganisms. Mycoplasma spp. are very small bacteria that can be found in the respiratory tract of many animals and humans. They can cause a variety of diseases, including pneumonia, meningitis, and arthritis.

(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 these microorganisms. Mycoplasma spp.