§ 866.3336 John Cunningham Virus serological reagents.

(a) Identification. John Cunningham Virus serological reagents are devices that consist of antigens and antisera used in serological assays to identify antibodies to John Cunningham Virus in serum and plasma. The identification aids in the risk stratification for the development of progressive multifocal leukoencephalopathy in multiple sclerosis and Crohn's disease patients undergoing natalizumab therapy. These devices are for adjunctive use, in the context of other clinical risk factors for the development of progressive multifocal leukoencephalopathy.

(b) Classification. Class II (special controls). The special control for this device is the FDA guideline document entitled “Class II Special Controls Guideline: John Cunningham Virus Serological Reagents.” For availability of the guideline document, see §866.1(e).

§ 866.3340 Klebsiella spp. serological reagents.

(a) Identification. Klebsiella spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), that are used in serological tests to identify Klebsiella spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus Klebsiella and provides epidemiological information on these diseases. These organisms can cause serious urinary tract and pulmonary infections, particularly in hospitalized patients.

(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.

§ 866.3350 Leptospira spp. serological reagents.

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

§ 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