§ 866.3085 Brucella spp. serological reagents.

(a) Identification. Brucella spp. serological reagents are devices that consist of antigens and antisera used for serological identification of Brucella spp. from cultured isolates derived from clinical specimens or to identify antibodies to Brucella spp. in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify Brucella spp. directly from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of brucellosis (e.g., undulant fever, Malta fever) caused by bacteria belonging to the genus Brucella and provides epidemiological information on these diseases. Chlamydia are the causative agents of psittacosis (a form of pneumonia), lymphogranuloma venereum (a venereal disease), and trachoma (a chronic disease of the eye and eyelid).

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

§ 866.3110 Campylobacter fetus serological reagents.

(a) Identification. Campylobacter fetus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Campylobacter fetus from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by this bacterium and provides epidemiological information on these diseases. Campylobacter fetus is a frequent cause of abortion in sheep and cattle and is sometimes responsible for endocarditis (inflammation of certain membranes of the heart) and enteritis (inflammation of the intestines) in humans.

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

§ 866.3115 Coccidioides immitis serological reagents.

(a) Identification. Coccidioides immitis serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Coccidioides immitis in serum. The identification aids in the diagnosis of coccidioidomycosis caused by a fungus
belonging to the genus *Coccidioides* and provides epidemiological information on diseases caused by this microorganism. An infection with *Coccidioides immitis* produces symptoms varying in severity from those accompanying the common cold to those of influenza.

(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 59226, Nov. 3, 1998]

§ 866.3140 *Corynebacterium* spp. serological reagents.

(a) *Identification*. *Corynebacterium* spp. serological reagents are devices that consist of antisera conjugated with a fluorescent dye used to identify *Corynebacterium* spp. from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Corynebacterium* and provides epidemiological information on diseases caused by these microorganisms. The principal human pathogen of this genus, *Corynebacterium diphtheriae*, causes diphtheria. However, many other types of corynebacteria form part of the normal flora of the human respiratory tract, other mucus membranes, and skin, and are either nonpathogenic or have an uncertain role.

(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.


§ 866.3145 *Coxsackievirus* serological reagents.

(a) *Identification*. *Coxsackievirus* serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Coxsackievirus* in serum. Additionally, some of these reagents consist of *Coxsackievirus* antisera conjugated with a fluorescent dye (immunofluorescent reagents) and are used to identify *Coxsackievirus* directly from clinical specimens or from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of *Coxsackievirus* and provides epidemiological information on this type of disease. *Coxsackievirus* infections are found most often as chronic meningitis (inflammation of brain membranes) and, if not treated, are usually fatal.

(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 59226, Nov. 3, 1998]

§ 866.315 Cytomegalovirus serological reagents.

(a) *Identification*. *Cytomegalovirus* serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Cytomegalovirus* in serum. The identification aids in the diagnosis of diseases caused by these viruses. *Cytomegalovirus* produces a variety of infections, including common colds, meningitis (inflammation of brain and spinal cord membranes), herpangina (brief fever accompanied by ulcerated lesions of the throat), and myopericarditis (inflammation of heart tissue).

(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.