clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Chlamydia* 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).

§ 866.3125 *Citrobacter* spp. serological reagents.

(a) Identification. *Citrobacter* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Citrobacter* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Citrobacter* and provides epidemiological information on diseases caused by these microorganisms. *Citrobacter* spp. have occasionally been associated with urinary tract infections.

(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]

§ 866.3145 *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 that are used to identify *Coxsackievirus* from clinical specimens or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of *Coxsackievirus* infections and provides epidemiological information on diseases caused by these viruses. *Coxsackieviruses* produce 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).