viruses. Equine encephalomyelitis viruses are transmitted to humans by the bite of insects, such as mosquitoes and ticks, and may cause encephalitis (inflammation of the brain), rash, acute arthritis, or hepatitis.

(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.


§ 866.3250 Erysipelothrix rhusiopathiae serological reagents.

(a) Identification. Erysipelothrix rhusiopathiae serological reagents are devices that consist of antigens and antisera used in serological tests to identify Erysipelothrix rhusiopathiae from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by this bacterium belonging to the genus Erysipelothrix. This organism is responsible for a variety of inflammations of the skin following skin abrasions from contact with fish, shellfish, or poultry.

(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.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25046, June 12, 1989; 66 FR 38791, July 25, 2001]

§ 866.3270 Flavobacterium spp. serological reagents.

(a) Identification. Flavobacterium spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify Flavobacterium spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus Flavobacterium and provides epidemiological information on diseases caused by these microorganisms. Most members of this genus are found in soil and water and, under certain conditions, may become pathogenic to humans. Flavobacterium meningosepticum is highly virulent for the newborn, in whom it may cause epidemics of septicemia (blood poisoning) and meningitis (inflammation of the membranes of the brain) and is usually attributable to contaminated hospital equipment.

(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.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25046, June 12, 1989; 66 FR 38792, July 25, 2001]

§ 866.3280 Francisella tularensis serological reagents.

(a) Identification. Francisella tularensis serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Francisella tularensis in serum or to identify Francisella tularensis in cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of antisera conjugated