§ 866.3850  
(b) Classification. Class II (performance standards).

§ 866.3850  Trichinella spiralis serological reagents.

(a) Identification. Trichinella spiralis serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Trichinella spiralis in serum. The identification aids in the diagnosis of trichinosis caused by parasitic roundworms belonging to the genus Trichinella and provides epidemiological information on trichinosis. Trichinosis is caused by ingestion of undercooked, infested meat, especially pork, and characterized by fever, muscle weakness, and diarrhea.

(b) Classification. Class II (performance standards).

§ 866.3930 Vibrio cholerae serological reagents.

(a) Identification. Vibrio cholerae serological reagents are devices that are used in the agglutination (an antigen-antibody clumping reaction) test to identify Vibrio cholerae from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of cholera caused by the bacterium Vibrio cholerae and provides epidemiological information on cholera. Cholera is an acute infectious disease characterized by severe diarrhea with extreme fluid and electrolyte (salts) depletion, and by vomiting, muscle cramps, and prostration. If untreated, the severe dehydration may lead to shock, renal failure, cardiovascular collapse, and death.

(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 59227, Nov. 3, 1998]

§ 866.3940 West Nile virus serological reagents.

(a) Identification. West Nile virus serological reagents are devices that consist of antigens and antisera for the detection of anti-West Nile virus IgM antibodies, in human serum, from individuals who have signs and symptoms consistent with viral meningitis/encephalitis. The detection aids in the clinical laboratory diagnosis of viral meningitis/encephalitis caused by West Nile virus.

(b) Classification. Class II (special controls). The special control is FDA's