Food and Drug Administration, HHS

(iv) EP5 “Evaluation of Precision Performance of Clinical Chemistry Devices, February 1999,” and
(2) Centers for Disease Control’s:
(i) Low Titer Rubella Standard,
(ii) Reference Panel of Well Characterized Rubella Sera, and
(3) World Health Organization’s International Rubella Standard.

§ 866.3520 Rubeola (measles) virus serological reagents.

(a) Identification. Rubeola (measles) virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to rubeola virus in serum. The identification aids in the diagnosis of measles and provides epidemiological information on the disease. Measles is an acute, highly infectious disease of the respiratory and reticuloendothelial tissues, particularly in children, characterized by a confluent and blotchy rash.

(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.

§ 866.3550 Salmonella spp. serological reagents.

(a) Identification. Salmonella spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify Salmonella spp. from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immuno-fluorescent reagents) used to identify Salmonella spp. directly from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of salmonellosis caused by bacteria belonging to the genus Salmonella and provides epidemiological information on this disease. Salmonellosis is characterized by high grade fever (“enteric fever”), severe diarrhea, and cramps.

(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.

§ 866.3630 Serratia spp. serological reagents.

(a) Identification. Serratia spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Serratia spp. in serum. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus Serratia and provides epidemiological information on these diseases. Serratia spp. are occasionally associated with gastroenteritis (food poisoning) and wound infections.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in