epidemiological information on German measles. Newborns infected in the uterus with rubella virus may be born with multiple congenital defects (rubella syndrome).

(b) **Classification.** Class II. The special controls for this device are:

1. National Committee for Clinical Laboratory Standards:
   - (i) 1/LA6 “Detection and Quantitation of Rubella IgG Antibody: Evaluation and Performance Criteria for Multiple Component Test Products, Specimen Handling, and Use of the Test Products in the Clinical Laboratory, October 1997.”
   - (ii) 1/LA18 “Specifications for Immunological Testing for Infectious Diseases, December 1994.”
   - (iii) D13 “Agglutination Characteristics, Methodology, Limitations, and Clinical Validation, October 1993.”
   - (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

§ 866.3600 **Schistosoma spp. serological reagents.**

(a) **Identification.** Schistosoma spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify Schistosoma spp. from cultured isolates derived from clinical specimens. Schistosomiasis caused by parasitic flatworms of the genus *Schistosoma.* Schistosomiasis is characterized by a variety of acute and chronic infections. Acute infection is marked by fever, allergic symptoms, and diarrhea. Chronic effects are usually severe and are caused by fibrous degeneration of tissue around deposited eggs of the parasite in the liver, lungs, and central nervous system. Schistosomes can also cause schistosome dermatitis (e.g., swimmer’s itch), a skin disease marked by intense itching.
§ 866.3630
(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 65 FR 2312, Jan. 14, 2000]

§ 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 Serratia spp. from cultured isolates. 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 subpart E of part 807 of this chapter subject to §866.9.

§ 866.3660 Shigella spp. serological reagents.
(a) Identification. Shigella spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify Shigella spp. from cultured isolates. The identification aids in the diagnosis of shigellosis caused by bacteria belonging to the genus Shigella and provides epidemiological information on this disease. Shigellosis is characterized by abdominal pain, cramps, diarrhea, and fever.
(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]

§ 866.3680 Sporothrix schenckii serological reagents.
(a) Identification. Sporothrix schenckii serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Sporothrix schenckii in serum. The identification aids in the diagnosis of sporotrichosis caused by a fungus belonging to the genus Sporothrix and provides epidemiological information on this disease. Sporotrichosis is a chronic tumorlike infection primarily of the skin.
(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 65 FR 2312, Jan. 14, 2000]

§ 866.3700 Staphylococcus aureus serological reagents.
(a) Identification. Staphylococcus aureus serological reagents are devices that consist of antigens and antisera used in serological tests to identify enterotoxin (toxin affecting the intestine) producing staphylococci from cultured isolates. The identification aids in the diagnosis of disease caused by this bacterium belonging to the genus Staphylococcus and provides epidemiological information on these diseases. Certain strains of Staphylococcus aureus produce an enterotoxin while growing in meat, dairy, or bakery products. After ingestion, this enterotoxin is absorbed in the gut and causes destruction of the intestinal lining (gastroenteritis).
(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.

§ 866.3720 Streptococcus spp. exoenzyme reagents.
(a) Identification. Streptococcus spp. exoenzyme reagents are devices used to identify antibodies to Streptococcus spp. exoenzyme in serum. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus Streptococcus and provides epidemiological information on these diseases. Pathogenic streptococci are associated with infections, such as sore