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.

§866.3600 Schistosoma spp. serological reagents.

(a) Identification. Schistosoma spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Schistosoma spp. in serum. The identification aids in the diagnosis of 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.

(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.

§866.3630 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 II (special 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.

§866.3660 Shigella spp. serological reagents.

(a) Identification. Shigella spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immuno-fluorescent reagents), 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.

§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 sporothricosis caused by a fungus belonging to the genus Sporothrix and provides epidemiological information on this disease. Sporothricosis 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.