

## § 866.3660

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 25047, June 12, 1989; 66 FR 38792, July 25, 2001]

### § 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 (immunofluorescent 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.

[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 sporothrichosis caused by a fungus belonging to the genus *Sporothrix* and provides epidemiological information on this disease. Sporothrichosis 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 intes-

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tine) 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.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25047, June 12, 1989; 66 FR 38792, July 25, 2001]

### § 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 throat, impetigo (an infection characterized by small pustules on the skin), urinary tract infections, rheumatic fever, and kidney disease.

(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 61 FR 1119, Jan. 16, 1996; 66 FR 38792, July 25, 2001]

### § 866.3740 *Streptococcus* spp. serological reagents.

(a) *Identification.* *Streptococcus* spp. serological reagents are devices that consist of antigens and antisera (excluding streptococcal exoenzyme reagents made from enzymes secreted by streptococci) used in serological tests to identify *Streptococcus* spp. from cultured isolates derived from clinical specimens. The identification aids in