§ 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 sporothrirosis caused by a fungus belonging to the genus Sporothrix and provides epidemiological information on this disease. Sporothrirosis 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 63 FR 59227, Nov. 3, 1998]

§ 866.3700 Staphylococcus aureus serological reagents.

(a) Identification. Staphylococcus aureus serological reagents are devices used to identify antibodies to Staphylococcus aureus in serum. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus Staphylococcus 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.


§ 866.3780 Toxoplasma gondii serological reagents.

(a) Identification. Toxoplasma gondii 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 Toxoplasma gondii from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus Toxoplasma 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 § 866.9.