Food and Drug Administration, HHS

§ 866.3830

Treponema pallidum treponemal test reagents.

(a) Identification. Treponema pallidum treponemal test reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Treponema pallidum directly from the bloodstream of infected patients. The identification aids in the diagnosis of syphilis caused by bacteria belonging to the genus Treponema and provides epidemiological information on syphilis.

(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 66 FR 38792, July 25, 2001]

§ 866.3820 Treponema pallidum nontreponemal test reagents.

(a) Identification. Treponema pallidum nontreponemal test reagents are devices that consist of antigens derived from nontreponemal sources (sources not directly associated with treponemal organisms) and control sera (standardized sera with which test results are compared) used in serological tests to identify reagin, an antibody-like agent, which is produced from the reaction of treponema microorganisms with body tissues. The identification aids in the diagnosis of syphilis caused by microorganisms belonging to the genus Treponema and provides epidemiological information on syphilis.

(b) Classification. Class II (performance standards).