Food and Drug Administration, HHS

§ 866.3175 Cytomegalovirus serological reagents.

(a) Identification. Cytomegalovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to cytomegalovirus in serum. The identification aids in the diagnosis of diseases caused by cytomegaloviruses and provides epidemiological information on diseases caused by these viruses. Cytomegaloviruses produce a variety of infections, including common colds, meningitis (inflammation of brain and spinal cord membranes), herpangina (brief fever accompanied by ulcerated lesions of the throat), and myopericarditis (inflammation of heart tissue).

(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.

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