§ 866.3205 Echovirus serological reagents.

(a) Identification. Echovirus serological reagents are devices that consist of echovirus antigens and antisera used in serological tests to identify echoviruses from clinical specimens or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of echovirus infections and provides epidemiological information on diseases caused by these viruses. Echoviruses cause illnesses such as meningitis (inflammation of the brain and spinal cord membranes), febrile illnesses (accompanied by fever) with or without rash, and the common cold.

(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.