§ 866.2120 Anaerobic chamber.

(a) Identification. An anaerobic chamber is a device intended for medical purposes to maintain an anaerobic (oxygen free) environment. It is used to isolate and cultivate anaerobic microorganisms.

(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.

§ 866.2160 Coagulase plasma.

(a) Identification. Coagulase plasma is a device that consists of freeze-dried animal or human plasma that is intended for medical purposes to perform coagulase tests primarily on staphylococcal bacteria. When reconstituted, the fluid plasma is clotted by the action of the enzyme coagulase which is produced by pathogenic staphylococci. Test results are used primarily as an aid in the diagnosis of disease caused by pathogenic bacteria belonging to the genus Staphylococcus and provide epidemiological information on disease caused by these microorganisms.

(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.

§ 866.2180 Manual colony counter.

(a) Identification. A manual colony counter is a device intended for medical purposes that consists of a printed grid system superimposed on an illuminated screen. Petri plates containing bacterial colonies to be counted are placed on the screen for better viewing and ease of counting. The number of colonies counted is used in the diagnosis of disease as a measure of the degree of bacterial infection.

(b) Classification. Class I (general controls). The device is exempt from the good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.

§ 866.2300 Multipurpose culture medium.

(a) Identification. A multipurpose culture medium is a device that consists primarily of liquid or solid biological materials intended for medical purposes for the cultivation and identification of several types of pathogenic microorganisms without the need of additional nutritional supplements.