§ 866.2170 Automated colony counter.
(a) Identification. An automated colony counter is a mechanical device intended for medical purposes to determine the number of bacterial colonies present on a bacteriological culture medium contained in a petri plate. 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 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 54 FR 25645, June 12, 1989; 66 FR 38790, July 25, 2001]

§ 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 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 54 FR 25645, June 12, 1989; 66 FR 38790, July 25, 2001]

§ 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. Test results aid in the diagnosis of disease and also provide epidemiological information on diseases caused by these microorganisms.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25645, June 12, 1989; 66 FR 38790, July 25, 2001]