§ 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.