§ 866.1 Scope.
(a) This part sets forth the classification of immunology and microbiology devices intended for human use that are in commercial distribution.
(b) The indentification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.
(c) To avoid duplicative listings, an immunology and microbiology device that has two or more types of uses (e.g., used both as a diagnostic device and as a microbiology device) is listed only in one subpart.
(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.
(e) Guidance documents referenced in this part are available on the Internet at http://www.fda.gov/cdrh/guidance.html.
Food and Drug Administration, HHS

§ 866.1620 Antimicrobial susceptibility test disc.

(a) Identification. An antimicrobial susceptibility test disc is a device that consists of antimicrobial-impregnated paper discs used to measure by a disc-agar diffusion technique or a disc-broth elution technique the in vitro susceptibility of most clinically important bacterial pathogens to antimicrobial...