

Food and Drug Administration, HHS

§ 866.3

- 866.5700 Whole human plasma or serum immunological test system.
- 866.5715 Plasminogen immunological test system.
- 866.5735 Prothrombin immunological test system.
- 866.5750 Radioallergosorbent (RAST) immunological test system.
- 866.5765 Retinol-binding protein immunological test system.
- 866.5775 Rheumatoid factor immunological test system.
- 866.5785 Anti-*Saccharomyces cerevisiae* (*S. cerevisiae*) antibody (ASCA) test systems.
- 866.5800 Seminal fluid (sperm) immunological test system.
- 866.5820 Systemic lupus erythematosus immunological test system.
- 866.5860 Total spinal fluid immunological test system.
- 866.5870 Thyroid autoantibody immunological test system.
- 866.5880 Transferrin immunological test system.
- 866.5890 Inter-*alpha* trypsin inhibitor immunological test system.
- 866.5900 Cystic fibrosis transmembrane conductance regulator (CFTR) gene mutation detection system.
- 866.5910 Quality control material for cystic fibrosis nucleic acid assays.

Subpart G—Tumor Associated Antigen Immunological Test Systems

- 866.6010 Tumor associated antigen immunological test system.
- 866.6020 Immunomagnetic circulating cancer cell selection and enumeration system.
- 866.6030 AFP-L3% immunological test system.
- 866.6040 Gene expression profiling test system for breast cancer prognosis.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 47 FR 50823, Nov. 9, 1982, unless otherwise noted.

Subpart A—General Provisions

§ 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 identification 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>.

[52 FR 17733, May 11, 1987, as amended at 68 FR 5827, Feb. 5, 2003]

§ 866.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (Premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraphs (b) and (c) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section