

**§ 864.9600**

**§ 864.9600 Potentiating media for in vitro diagnostic use.**

(a) *Identification.* Potentiating media for in vitro diagnostic use are media, such as bovine albumin, that are used to suspend red cells and to enhance cell reactions for antigen-antibody testing.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60649, Sept. 12, 1980, as amended at 63 FR 59226, Nov. 3, 1998]

**§ 864.9650 Quality control kit for blood banking reagents.**

(a) *Identification.* A quality control kit for blood banking reagents is a device that consists of sera, cells, buffers, and antibodies used to determine the specificity, potency, and reactivity of the cells and reagents used for blood banking.

(b) *Classification.* Class II (performance standards).

[45 FR 60649, Sept. 12, 1980]

**§ 864.9700 Blood storage refrigerator and blood storage freezer.**

(a) *Identification.* A blood storage refrigerator and a blood storage freezer are devices intended for medical purposes that are used to preserve blood and blood products by storing them at cold or freezing temperatures.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60650, Sept. 12, 1980, as amended at 63 FR 59226, Nov. 3, 1998]

**§ 864.9750 Heat-sealing device.**

(a) *Identification.* A heat-sealing device is a device intended for medical purposes that uses heat to seal plastic bags containing blood or blood components.

(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 § 864.9.

[45 FR 60650, Sept. 12, 1980, as amended at 65 FR 2311, Jan. 14, 2000]

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**§ 864.9875 Transfer set.**

(a) *Identification.* A transfer set is a device intended for medical purposes that consists of a piece of tubing with suitable adaptors used to transfer blood or plasma from one container to another.

(b) *Classification.* Class II (performance standards).

[45 FR 60651, Sept. 12, 1980]

**PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES**

**Subpart A—General Provisions**

Sec.

866.1 Scope.

866.3 Effective dates of requirement for premarket approval.

866.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

**Subpart B—Diagnostic Devices**

866.1620 Antimicrobial susceptibility test disc.

866.1640 Antimicrobial susceptibility test powder.

866.1645 Fully automated short-term incubation cycle antimicrobial susceptibility system.

866.1700 Culture medium for antimicrobial susceptibility tests.

**Subpart C—Microbiology Devices**

866.2050 Staphylococcal typing bacteriophage.

866.2120 Anaerobic chamber.

866.2160 Coagulase plasma.

866.2170 Automated colony counter.

866.2180 Manual colony counter.

866.2300 Multipurpose culture medium.

866.2320 Differential culture medium.

866.2330 Enriched culture medium.

866.2350 Microbiological assay culture medium.

866.2360 Selective culture medium.

866.2390 Transport culture medium.

866.2410 Culture medium for pathogenic *Neisseria* spp.

866.2420 Oxidase screening test for gonorrhea.

866.2440 Automated medium dispensing and stacking device.

866.2450 Supplement for culture media.

866.2480 Quality control kit for culture media.

866.2500 Microtiter diluting and dispensing device.

866.2540 Microbiological incubator.

866.2560 Microbial growth monitor.