

§ 864.3300

21 CFR Ch. I (4–1–13 Edition)

§ 864.3300 Cytocentrifuge.

(a) *Identification.* A cytocentrifuge is a centrifuge used to concentrate cells from biological cell suspensions (e.g., cerebrospinal fluid) and to deposit these cells on a glass microscope slide for cytological examination.

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

[45 FR 60588, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989; 66 FR 38789, July 25, 2001]

§ 864.3400 Device for sealing microsections.

(a) *Identification.* A device for sealing microsections is an automated instrument used to seal stained cells and microsections for histological and cytological examination.

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

[45 FR 60589, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989; 66 FR 38789, July 25, 2001]

§ 864.3600 Microscopes and accessories.

(a) *Identification.* Microscopes and accessories are optical instruments used to enlarge images of specimens, preparations, and cultures for medical purposes. Variations of microscopes and accessories (through a change in the light source) used for medical purposes include the following:

(1) Phase contrast microscopes, which permit visualization of unstained preparations by altering the phase relationship of light that passes around the object and through the object.

(2) Fluorescence microscopes, which permit examination of specimens stained with fluorochromes that fluoresce under ultraviolet light.

(3) Inverted stage microscopes, which permit examination of tissue cultures or other biological specimens contained in bottles or tubes with the light source mounted above the specimen.

(b) *Classification.* Class I (general controls). These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 60590, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989; 66 FR 38789, July 25, 2001]

§ 864.3800 Automated slide stainer.

(a) *Identification.* An automated slide stainer is a device used to stain histology, cytology, and hematology slides for diagnosis.

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

[45 FR 60591, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989; 66 FR 38789, July 25, 2001]

§ 864.3875 Automated tissue processor.

(a) *Identification.* An automated tissue processor is an automated system used to process tissue specimens for examination through fixation, dehydration, and infiltration.

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

[45 FR 60591, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989; 66 FR 38789, July 25, 2001]

Subpart E—Specimen Preparation Reagents

§ 864.4010 General purpose reagent.

(a) A general purpose reagent is a chemical reagent that has general laboratory application, that is used to collect, prepare, and examine specimens from the human body for diagnostic purposes, and that is not labeled or

otherwise intended for a specific diagnostic application. It may be either an individual substance, or multiple substances reformulated, which, when combined with or used in conjunction with an appropriate analyte specific reagent (ASR) and other general purpose reagents, is part of a diagnostic test procedure or system constituting a finished in vitro diagnostic (IVD) test. General purpose reagents are appropriate for combining with one or more than one ASR in producing such systems and include labware or disposable constituents of tests; but they do not include laboratory machinery, automated or powered systems. General purpose reagents include cytological preservatives, decalcifying reagents, fixative and adhesives, tissue processing reagents, isotonic solutions and pH buffers. Reagents used in tests for more than one individual chemical substance or ligand are general purpose reagents (e.g., *Thermus aquaticus* (TAQ) polymerase, substrates for enzyme immunoassay (EIA)).

(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 § 864.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 60592, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989; 62 FR 62260, Nov. 21, 1997; 66 FR 38789, July 25, 2001]

§ 864.4020 Analyte specific reagents.

(a) *Identification*. Analyte specific reagents (ASR's) are antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid sequences, and similar reagents which, through specific binding or chemical reaction with substances in a specimen, are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens. ASR's that otherwise fall within this definition are not

within the scope of subpart E of this part when they are sold to:

(1) In vitro diagnostic manufacturers; or

(2) Organizations that use the reagents to make tests for purposes other than providing diagnostic information to patients and practitioners, e.g., forensic, academic, research, and other nonclinical laboratories.

(b) *Classification*. (1) Class I (general controls). Except as described in paragraphs (b)(2) and (b)(3) of this section, these devices are exempt from the premarket notification requirements in part 807, subpart E of this chapter.

(2) Class II (special controls/guidance documents), when the analyte is used in blood banking tests that have been classified as class II devices (e.g., certain cytomegalovirus serological and *treponema pallidum nontreponemal* test reagents). Guidance Documents:

1. "Specifications for Immunological Testing for Infectious Disease; Approved Guideline," NCCLS Document I/LA18-A, December 1994.

2. "Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristic (ROC) Plots; Tentative Guideline," NCCLS Document KGP10-T, December 1993.

3. "Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of *Mycobacterium* spp.," FDA, July 6, 1993, and its "Attachment 1," February 28, 1994.

4. "Draft Review Criteria for Nucleic Acid Amplification-Based In Vitro Diagnostic Devices for Direct Detection of Infectious Microorganisms," FDA, July 6, 1993.

5. The Center for Biologics Evaluation and Research, FDA, "Points to Consider in the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Antibodies to the Human Immunodeficiency Virus, Type I" (54 FR 48943, November 28, 1989).

(3) Class III (premarket approval), when:

(i) The analyte is intended as a component in a test intended for use in the diagnosis of a contagious condition that is highly likely to result in a fatal outcome and prompt, accurate diagnosis offers the opportunity to mitigate the public health impact of the condition (e.g., human immunodeficiency virus (HIV/AIDS) or tuberculosis (TB)); or

(ii) The analyte is intended as a component in a test intended for use in