§ 862.2540 Flame emission photometer for clinical use.

(a) Identification. A flame emission photometer for clinical use is a device intended to measure the concentration of sodium, potassium, lithium, and other metal ions in body fluids. Abnormal variations in the concentration of these substances in the body are indicative of certain disorders (e.g., electrolyte imbalance and heavy metal intoxication) and are, therefore, useful in diagnosis and treatment of these disorders.

(b) Classification. Class I.

§ 862.2560 Fluorometer for clinical use.

(a) Identification. A fluorometer for clinical use is a device intended to measure by fluorescence certain analytes. Fluorescence is the property of certain substances of radiating, when illuminated, a light of a different wavelength. This device is used in conjunction with certain materials to measure a variety of analytes.

(b) Classification. Class I.

§ 862.2680 Microtitrator for clinical use.

(a) Identification. A microtitrator for clinical use is a device intended for use in micronanalysis to measure the concentration of a substance by reacting it with a measure “micro” volume of a known standardized solution.

(b) Classification. Class I.

§ 862.2700 Nephelometer for clinical use.

(a) Identification. A nephelometer for clinical use is a device intended to estimate the concentration of particles in a suspension by measuring their light scattering properties (the deflection of light rays by opaque particles in their path). The device is used in conjunction with certain materials to measure the concentration of a variety of analytes.

(b) Classification. Class I.

§ 862.2720 Plasma oncometer for clinical use.

(a) Identification. A plasma oncometer for clinical use is a device intended to measure plasma oncotic pressure, which is that portion of the total plasma osmotic pressure contributed by protein and other molecules too large to pass through a specified semipermeable membrane. Because variations in plasma oncotic pressure are indications of certain disorders, measurements of the variations are useful in the diagnosis and treatment of these disorders.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 16122, May 1, 1987, as amended at 60 FR 38900, July 28, 1995]

§ 862.2730 Osmometer for clinical use.

(a) Identification. An osmometer for clinical use is a device intended to measure the osmotic pressure of body fluids. Osmotic pressure is the pressure required to prevent the passage of a solution with a lesser solute concentration into a solution with greater solute concentration when the two solutions are separated by a semipermeable membrane. The concentration of a solution affects its osmotic pressure, freezing point, and other physiochemical properties. Osmometers determine osmotic pressure by methods such as the measurement of the freezing point. Measurements obtained by this device are used in the diagnosis and treatment of body fluid disorders.

(b) Classification. Class I.

§ 862.2750 Pipetting and diluting system for clinical use.

(a) Identification. A pipetting and diluting system for clinical use is a device intended to provide an accurately measured volume of liquid at a specified temperature for use in certain test procedures. This generic type of device system includes serial, manual, automated, and semi-automated dilutors, pipettors, dispensers, and pipetting stations.

(b) Classification. Class I.

§ 862.2800 Refractometer for clinical use.

(a) Identification. A refractometer for clinical use is a device intended to determine the amount of solute in a solution by measuring the index of refraction (the ratio of the velocity of light in a vacuum to the velocity of light in
the solution). The index of refraction is used to measure the concentration of certain analytes (solutes), such as plasma total proteins and urinary total solids. Measurements obtained by this device are used in the diagnosis and treatment of certain conditions.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

§ 862.2850 Atomic absorption spectrophotometer for clinical use.

(a) Identification. An atomic absorption spectrophotometer for clinical use is a device intended to identify and measure elements and metals (e.g., lead and mercury) in human specimens. The metal elements are identified according to the wavelength and intensity of the light that is absorbed when the specimen is converted to the atomic vapor phase. Measurements obtained by this device are used in the diagnosis and treatment of certain conditions.

(b) Classification. Class I.

§ 862.2860 Mass spectrometer for clinical use.

(a) Identification. A mass spectrometer for clinical use is a device intended to identify inorganic or organic compounds (e.g., lead, mercury, and drugs) in human specimens by ionizing the compound under investigation and separating the resulting ions by means of an electrical and magnetic field according to their mass.

(b) Classification. Class I.

§ 862.2900 Automated urinalysis system.

(a) Identification. An automated urinalysis system is a device intended to measure certain of the physical properties and chemical constituents of urine by procedures that duplicate manual urinalysis systems. This device is used in conjunction with certain materials to measure a variety of urinary analytes.

(b) Classification. Class I.

§ 862.2920 Plasma viscometer for clinical use.

(a) Identification. A plasma viscometer for clinical use is a device intended to measure the viscosity of plasma by determining the time period required for the plasma to flow a measured distance through a calibrated glass tube. Measurements obtained by this device are used to monitor changes in the amount of solids present in plasma in various disorders.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

Subpart D—Clinical Toxicology Test Systems

§ 862.3030 Acetaminophen test system.

(a) Identification. An acetaminophen test system is a device intended to measure acetaminophen, an analgesic and fever reducing drug, in serum. Measurements obtained by this device are used in the diagnosis and treatment of acetaminophen overdose.

(b) Classification. Class II.

§ 862.3035 Amikacin test system.

(a) Identification. An amikacin test system is a device intended to measure amikacin, an aminoglycoside antibiotic drug, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of amikacin overdose and in monitoring levels of amikacin to ensure appropriate therapy.

(b) Classification. Class II.

§ 862.3040 Alcohol test system.

(a) Identification. An alcohol test system is a device intended to measure alcohol (e.g., ethanol, methanol, isopropanol, etc.) in human body fluids (e.g., serum, whole blood, and urine). Measurements obtained by this device are used in the diagnosis and treatment of alcohol intoxication and poisoning.

(b) Classification. Class II.
§ 862.3050 Breath-alcohol test system.
(a) Identification. A breath-alcohol test system is a device intended to measure alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.
(b) Classification. Class I.

§ 862.3100 Amphetamine test system.
(a) Identification. An amphetamine test system is a device intended to measure amphetamine, a central nervous system stimulating drug, in plasma and urine. Measurements obtained by this device are used in the diagnosis and treatment of amphetamine use or overdose and in monitoring levels of amphetamine to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3110 Antimony test system.
(a) Identification. An antimony test system is a device intended to measure antimony, a heavy metal, in urine, blood, vomitus, and stomach contents. Measurements obtained by this device are used in the diagnosis and treatment of antimony poisoning.
(b) Classification. Class I.

§ 862.3120 Arsenic test system.
(a) Identification. An arsenic test system is a device intended to measure arsenic, a poisonous heavy metal, in urine, vomitus, stomach contents, nails, hair, and blood. Measurements obtained by this device are used in the diagnosis and treatment of arsenic poisoning.
(b) Classification. Class I.

§ 862.3150 Barbiturate test system.
(a) Identification. A barbiturate test system is a device intended to measure barbiturates, a class of hypnotic and sedative drugs, in serum, urine, and gastric contents. Measurements obtained by this device are used in the diagnosis and treatment of barbiturate use or overdose and in monitoring levels of barbiturate to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3170 Benzodiazepine test system.
(a) Identification. A benzodiazepine test system is a device intended to measure any of the benzodiazepine compounds, sedative and hypnotic drugs, in blood, plasma, and urine. The benzodiazepine compounds include chlordiazepoxide, diazepam, oxazepam, clorazepate, flurazepam, and nitrazepam. Measurements obtained by this device are used in the diagnosis and treatment of benzodiazepine use or overdose and in monitoring levels of benzodiazepines to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3200 Clinical toxicology calibrator.
(a) Identification. A clinical toxicology calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens. A clinical toxicology calibrator can be a mixture of drugs or a specific material for a particular drug (e.g., ethanol, lidocaine, etc.). (See also § 862.2 in this part.)
(b) Classification. Class II.

§ 862.3220 Carbon monoxide test system.
(a) Identification. A carbon monoxide test system is a device intended to measure carbon monoxide or carboxyhemoglobin (carbon monoxide bound to the hemoglobin in the blood) in blood. Measurements obtained by this device are used in the diagnosis and treatment of or confirmation of carbon monoxide poisoning.
(b) Classification. Class I.

§ 862.3240 Cholinesterase test system.
(a) Identification. A cholinesterase test system is a device intended to measure cholinesterase (an enzyme that catalyzes the hydrolysis of acetylcholine to choline) in human specimens. There are two principal types of cholinesterase in human tissues. True cholinesterase is present at nerve endings and in erythrocytes (red blood cells) but is not present in plasma. Pseudo cholinesterase is present in plasma and liver but is not present in
§ 862.3250  Cocaine and cocaine metabolite test system.
(a) Identification. A cocaine and cocaine metabolite test system is a device intended to measure cocaine and a cocaine metabolite (benzoylecgonine) in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of cocaine use or overdose.
(b) Classification. Class II.

§ 862.3270  Codeine test system.
(a) Identification. A codeine test system is a device intended to measure codeine (a narcotic pain-relieving drug) in serum and urine. Measurements obtained by this device are used in the diagnosis and treatment of codeine use or overdose and in monitoring levels of codeine to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3280  Clinical toxicology control material.
(a) Identification. A clinical toxicology control material is a device intended to provide an estimation of the precision of a device test system and to detect and monitor systematic deviations from accuracy resulting from reagent or instrument defects. This generic type of device includes various single, and multi-analyte control materials.
(b) Classification. Class I.

§ 862.3300  Digitoxin test system.
(a) Identification. A digitoxin test system is a device intended to measure digitoxin, a cardiovascular drug, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of digitoxin overdose and in monitoring levels of digitoxin to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3320  Digoxin test system.
(a) Identification. A digoxin test system is a device intended to measure digoxin, a cardiovascular drug, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of digoxin overdose and in monitoring levels of digoxin to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3350  Diphenylhydantoin test system.
(a) Identification. A diphenylhydantoin test system is a device intended to measure diphenylhydantoin, an antiepileptic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of diphenylhydantoin overdose and in monitoring levels of diphenylhydantoin to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3380  Ethosuximide test system.
(a) Identification. An ethosuximide test system is a device intended to measure ethosuximide, an antiepileptic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of ethosuximide overdose and in monitoring levels of ethosuximide to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3450  Gentamicin test system.
(a) Identification. A gentamicin test system is a device intended to measure gentamicin, an antibiotic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of gentamicin overdose and in monitoring levels of gentamicin to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3520  Kanamycin test system.
(a) Identification. A kanamycin test system is a device intended to measure kanamycin, an antibiotic drug, in plasma and serum. Measurements obtained by this device are used in the diagnosis and treatment of kanamycin overdose and in monitoring levels of kanamycin to ensure appropriate therapy.
(b) Classification. Class II.
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§ 862.3550 Lead test system.
(a) Identification. A lead test system is a device intended to measure lead, a heavy metal, in blood and urine. Measurements obtained by this device are used in the diagnosis and treatment of lead poisoning.
(b) Classification. Class II.

§ 862.3555 Lidocaine test system.
(a) Identification. A lidocaine test system is a device intended to measure lidocaine, an antiarrythmic and anticonvulsant drug, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of lidocaine overdose or in monitoring levels of lidocaine to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3560 Lithium test system.
(a) Identification. A lithium test system is a device intended to measure lithium (from the drug lithium carbonate) in serum or plasma. Measurements of lithium are used to assure that the proper drug dosage is administered to the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).
(b) Classification. Class II.

§ 862.3580 Lysergic acid diethylamide (LSD) test system.
(a) Identification. A lysergic acid diethylamide (LSD) test system is a device intended to measure lysergic acid diethylamide, a hallucinogenic drug, in serum, urine, and gastric contents. Measurements obtained by this device are used in the diagnosis and treatment of LSD use or overdose.
(b) Classification. Class II.

§ 862.3600 Mercury test system.
(a) Identification. A mercury test system is a device intended to measure mercury, a heavy metal, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of mercury poisoning.
(b) Classification. Class I.

§ 862.3610 Methamphetamine test system.
(a) Identification. A methamphetamine test system is a device intended to measure methamphetamine, a central nervous system stimulating drug, in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of methamphetamine use or overdose.
(b) Classification. Class II.

§ 862.3620 Methadone test system.
(a) Identification. A methadone test system is a device intended to measure methadone, an addictive narcotic pain-relieving drug, in serum and urine. Measurements obtained by this device are used in the diagnosis and treatment of methadone use or overdose and to determine compliance with regulations in methadone maintenance treatment.
(b) Classification. Class II.

§ 862.3630 Methaqualone test system.
(a) Identification. A methaqualone test system is a device intended to measure methaqualone, a hypnotic and sedative drug, in urine. Measurements obtained by this device are used in the diagnosis and treatment of methaqualone use or overdose.
(b) Classification. Class II.

§ 862.3640 Morphine test system.
(a) Identification. A morphine test system is a device intended to measure morphine, an addictive narcotic pain-relieving drug, and its analogs in serum, urine, and gastric contents. Measurements obtained by this device are used in the diagnosis and treatment of morphine use or overdose and in monitoring levels of morphine and its analogs to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3645 Neuroleptic drugs radioreceptor assay test system.
(a) Identification. A neuroleptic drugs radioreceptor assay test system is a device intended to measure in serum or plasma the dopamine receptor blocking activity of neuroleptic drugs and their active metabolites. A neuroleptic drug has anti-psychotic action affecting principally psychomotor activity, is generally without hypnotic effects, and is a tranquilizer. Measurements obtained by this device are used to aid in
§ 862.3650 Opiate test system.
(a) Identification. An opiate test system is a device intended to measure any of the addictive narcotic pain-relieving opiate drugs in blood, serum, urine, gastric contents, and saliva. An opiate is any natural or synthetic drug that has morphine-like pharmacological actions. The opiates include drugs such as morphine, morphine glucoronide, heroin, codeine, nalorphine, and meperidine. Measurements obtained by this device are used in the diagnosis and treatment of opiate use or overdose and in monitoring the levels of opiate administration to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3660 Phenobarbital test system.
(a) Identification. A phenobarbital test system is a device intended to measure phenobarbital, an antiepileptic and sedative-hypnotic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of phenobarbital use or overdose and in monitoring levels of phenobarbital to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3670 Phenothiazine test system.
(a) Identification. A phenothiazine test system is a device intended to measure any of the drugs of the phenothiazine class in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of phenothiazine use or overdose.
(b) Classification. Class II.

§ 862.3680 Primidone test system.
(a) Identification. A primidone test system is a device intended to measure primidone, an antiepileptic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of primidone overdose and in monitoring levels of primidone to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3700 Propoxyphene test system.
(a) Identification. A propoxyphene test system is a device intended to measure propoxyphene, a pain-relieving drug, in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of propoxyphene use or overdose or in monitoring levels of propoxyphene to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3750 Quinine test system.
(a) Identification. A quinine test system is a device intended to measure quinine, a fever-reducing and pain-relieving drug intended in the treatment of malaria, in serum and urine. Measurements obtained by this device are used in the diagnosis and treatment of quinine overdose and malaria.
(b) Classification. Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

§ 862.3830 Salicylate test system.
(a) Identification. A salicylate test system is a device intended to measure salicylates, a class of analgesic, antipyretic and anti-inflammatory drugs that includes aspirin, in human specimens. Measurements obtained by this device are used in diagnosis and treatment of salicylate overdose and in monitoring salicylate levels to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3850 Sulfonamide test system.
(a) Identification. A sulfonamide test system is a device intended to measure sulfonamides, any of the antibacterial drugs derived from sulfanilamide, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of sulfonamide overdose and in monitoring sulfonamide levels to ensure appropriate therapy.
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§ 862.3870 Cannabinoid test system.
(a) Identification. A cannabinoid test system is a device intended to measure any of the cannabinoids, hallucinogenic compounds endogenous to marijuana, in serum, plasma, saliva, and urine. Cannabinoid compounds include delta-9-tetrahydrocannabinol, cannabidiol, cannabinol, and cannabichromene. Measurements obtained by this device are used in the diagnosis and treatment of cannabinoid use or abuse and in monitoring levels of cannabinoids during clinical investigational use.
(b) Classification. Class II.

§ 862.3880 Theophylline test system.
(a) Identification. A theophylline test system is a device intended to measure theophylline (a drug used for stimulation of the muscles in the cardiovascular, respiratory, and central nervous systems) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of theophylline overdose or in monitoring levels of theophylline to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3900 Tobramycin test system.
(a) Identification. A tobramycin test system is a device intended to measure tobramycin, an aminoglycoside antibiotic drug, in plasma and serum. Measurements obtained by this device are used in the diagnosis and treatment of tobramycin overdose and in monitoring levels of tobramycin to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3910 Tricyclic antidepressant drugs test system.
(a) Identification. A tricyclic antidepressant drugs test system is a device intended to measure any of the tricyclic antidepressant drugs in serum. The tricyclic antidepressant drugs include imipramine, desipramine, amitriptyline, nortriptyline, protriptyline, and doxepin. Measurements obtained by this device are used in the diagnosis and treatment of chronic depression to ensure appropriate therapy.
(b) Classification. Class II.

§ 862.3950 Vancomycin test system.
(a) Identification. A vancomycin test system is a device intended to measure vancomycin, an antibiotic drug, in serum. Measurements obtained by this device are used in the diagnosis and treatment of vancomycin overdose and in monitoring the level of vancomycin to ensure appropriate therapy.
(b) Classification. Class II.

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

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Subpart A—General Provisions

§ 864.1 Scope.

(a) This part sets forth the classification of hematology and pathology 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) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

[52 FR 17732, May 11, 1987]

§ 864.3 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 paragraph (b) 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 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

[52 FR 17732, May 11, 1987]
§ 864.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The Food and Drug Administration’s (FDA’s) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device’s safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976, e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

[54 FR 25043, June 12, 1989]

Subpart B—Biological Stains

§ 864.1850 Dye and chemical solution stains.

(a) Identification. Dye and chemical solution stains for medical purposes are mixtures of synthetic or natural dyes or nondenatured chemicals in solutions used in staining cells and tissues for diagnostic histopathology, cytopathology, or hematology.

(b) Classification. Class I. These devices are exempt from the premarket notification procedures in Subpart E of Part 807. The devices are also exempt from the current good manufacturing practice regulations 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 60583, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989]

Subpart C—Cell And Tissue Culture Products

§ 864.2220 Synthetic cell and tissue culture media and components.

(a) Identification. Synthetic cell and tissue culture media and components are substances that are composed entirely of defined components (e.g., amino acids, vitamins, inorganic salts, etc.) that are essential for the survival and development of cell lines of humans and other animals.

(b) Classification. Class I. These devices are exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

[45 FR 60583, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989]

§ 864.2240 Cell and tissue culture supplies and equipment.

(a) Identification. Cell and tissue culture supplies and equipment are devices that are used to examine, propagate, nourish, or grow cells and tissue cultures. These include such articles as slide culture chambers, perfusion and roller apparatus, cell culture suspension systems, and tissue culture flasks, dishes, tubes, and roller bottles.

(b) Classification. Class I. These devices are exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter. If the devices are not labeled or otherwise represented as sterile, they are exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records.
§ 864.2260 Chromosome culture kit.
(a) Identification. A chromosome culture kit is a device containing the necessary ingredients (e.g., Minimum Essential Media (MEM) of McCoy's 5A culture media, phytohemagglutinin, fetal calf serum, antibiotics, and heparin) used to culture tissues for diagnosis of congenital chromosome abnormalities.
(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of Part 807 of this chapter.

[45 FR 60585, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989]

§ 864.2280 Cultured animal and human cells.
(a) Identification. Cultured animal and human cells are in vitro cultivated cell lines from the tissue of humans or other animals which are used in various diagnostic procedures, particularly diagnostic virology and cytogenetic studies.
(b) Classification. Class I (general controls).

[45 FR 60585, Sept. 12, 1980]

§ 864.2360 Mycoplasma detection media and components.
(a) Identification. Mycoplasma detection media and components are used to detect and isolate mycoplasma pleuropneumonia-like organisms (PPLO), a common microbial contaminant in cell cultures.
(b) Classification. Class I. These devices are exempt from the premarket notification procedures in subpart E of Part 807 of this chapter.

[45 FR 60586, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989]

§ 864.2800 Animal and human sera.
(a) Identification. Animal and human sera are biological products, obtained from the blood of humans or other animals, that provide the necessary growth-promoting nutrients in a cell culture system.

(b) Classification. Class I. The devices are exempt from the premarket notification procedures in subpart E of Part 807 of this chapter.

[45 FR 60586, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989]

§ 864.3250 Specimen transport and storage container.
(a) Identification. A specimen transport and storage container, which may be empty or prefilled, is a device intended to contain biological specimens, body waste, or body exudate during storage and transport in order that the...
§ 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. The device is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

[54 FR 60588, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989]

§ 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. The device is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

[54 FR 60589, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989]

§ 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. These devices are exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

[54 FR 60590, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989]

§ 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. The device is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

[54 FR 60591, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989]

§ 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. The device is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

[54 FR 60591, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989]
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Subpart E—Specimen Preparation

Reagents
§ 864.4010 General purpose reagent.

(a) Identification. 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 histopathology, cytology, and hematology, and that is not labeled or otherwise intended for a specific diagnostic application. General purpose reagents include cytological preservatives, decalcifying reagents, fixatives and adhesives, tissue processing reagents, isotonic solutions, and pH buffers.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations 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]

§ 864.4400 Enzyme preparations.

(a) Identification. Enzyme preparations are products that are used in the histopathology laboratory for the following purposes:

(1) To disaggregate tissues and cells already in established cultures for preparation into subsequent cultures (e.g., trypsin);

(2) To disaggregate fluid specimens for cytological examination (e.g., papain for gastric lavage or trypsin for sputum liquefaction);

(3) To aid in the selective staining of tissue specimens (e.g., diastase for glycogen determination).

(b) Classification. Class I. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.
[45 FR 60592, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989]

Subpart F—Automated and Semi-Automated Hematology Devices

§ 864.5200 Automated cell counter.

(a) Identification. An automated cell counter is a fully-automated or semi-automated device used to count red blood cells, white blood cells, or blood platelets using a sample of the patient's peripheral blood (blood circulating in one of the body's extremities, such as the arm). These devices may also measure hemoglobin or hematocrit and may also calculate or measure one or more of the red cell indices (the erythrocyte mean corpuscular volume, the mean corpuscular hemoglobin, or the mean corpuscular hemoglobin concentration). These devices may use either an electronic particle counting method or an optical counting method.

(b) Classification. Class II (performance standards).
[45 FR 60593, Sept. 12, 1980]

§ 864.5220 Automated differential cell counter.

(a) Identification. An automated differential cell counter is a device used to identify and classify one or more of the formed elements of the blood.

(b) Classification. (1) Class II (performance standards) when the device is intended to flag or identify specimens containing abnormal blood cells.

(2) Class III (premarket approval) when the device is intended for other uses, including to count or classify abnormal cells of the blood.

(c) Date PMA or notice of completion of a PDP is required. No effective date has been established of the requirement for premarket approval for the device identified in paragraph (b)(2) of this section. See §864.3.
[45 FR 60596, Sept. 12, 1980, as amended at 55 FR 23511, June 8, 1990]

§ 864.5240 Automated blood cell diluting apparatus.

(a) Identification. An automated blood cell diluting apparatus is a fully automated or semi-automated device used to make appropriate dilutions of a blood sample for further testing.

(b) Classification. Class I (general controls).
[45 FR 60596, Sept. 12, 1980]
§ 864.5260 Automated cell-locating device.

(a) Identification. An automated cell-locating device is a device used to locate blood cells on a peripheral blood smear, allowing the operator to identify and classify each cell according to type. (Peripheral blood is blood circulating in one of the body's extremities, such as the arm.)

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

[45 FR 60597, Sept. 12, 1980]

§ 864.5300 Red cell indices device.

(a) Identification. A red cell indices device, usually part of a larger system, calculates or directly measures the erythrocyte mean corpuscular volume (MCV), the mean corpuscular hemoglobin (MCH), and the mean corpuscular hemoglobin concentration (MCHC). The red cell indices are used for the differential diagnosis of anemias.

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

[45 FR 60597, Sept. 12, 1980]

§ 864.5350 Microsedimentation centrifuge.

(a) Identification. A microsedimentation centrifuge is a device used to sediment red cells for the microsedimentation rate test.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.


§ 864.5400 Coagulation instrument.

(a) Identification. A coagulation instrument is an automated or semiautomated device used to determine the onset of clot formation for in vitro coagulation studies.

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

[45 FR 60598, Sept. 12, 1980]

§ 864.5425 Multipurpose system for in vitro coagulation studies.

(a) Identification. A multipurpose system for in vitro coagulation studies is a device consisting of one automated or semiautomated instrument and its associated reagents and controls. The system is used to perform a series of coagulation studies and coagulation factor assays.

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

[45 FR 60599, Sept. 12, 1980]

§ 864.5600 Automated hematocrit instrument.

(a) Identification. An automated hematocrit instrument is a fully automated or semi-automated device which may or may not be part of a larger system. This device measures the packed red cell volume of a blood sample to distinguish normal from abnormal states, such as anemia and erythrocytosis (an increase in the number of red cells).

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

[45 FR 60600, Sept. 12, 1980]

§ 864.5620 Automated hemoglobin system.

(a) Identification. An automated hemoglobin system is a fully automated or semi-automated device which may or may not be part of a larger system. The generic type of device consists of the reagents, calibrators, controls, and instrumentation used to determine the hemoglobin content of human blood.

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

[45 FR 60601, Sept. 12, 1980]

§ 864.5680 Automated heparin analyzer.

(a) Identification. An automated heparin analyzer is a device used to determine the heparin level in a blood sample by mixing the sample with protamine (a heparin-neutralizing substance) and determining photometrically the onset of air-activated clotting. The analyzer also determines the amount of protamine necessary to neutralize the heparin in the patient's circulation.

(b) Classification. Class II (special controls).

§ 864.5700 Automated platelet aggregation system.

(a) Identification. An automated platelet aggregation system is a device used to determine changes in platelet shape and platelet aggregation following the addition of an aggregating reagent to a platelet-rich plasma.

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

[45 FR 60602, Sept. 12, 1980]

§ 864.5800 Automated sedimentation rate device.

(a) Identification. An automated sedimentation rate device is an instrument that measures automatically the erythrocyte sedimentation rate in whole blood. Because an increased sedimentation rate indicates tissue damage or inflammation, the erythrocyte sedimentation rate device is useful in monitoring treatment of a disease.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

[45 FR 60602, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989]

§ 864.5850 Automated slide spinner.

(a) Identification. An automated slide spinner is a device that prepares automatically a blood film on a microscope slide using a small amount of peripheral blood (blood circulating in one of the body’s extremities, such as the arm).

(b) Classification. Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

[45 FR 60603, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989]

§ 864.5950 Blood volume measuring device.

(a) Identification. A blood volume measuring device is a manual, semi-automated, or automated system that is used to calculate the red cell mass, plasma volume, and total blood volume.

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

[45 FR 60603, Sept. 12, 1980]

Subpart G—Manual Hematology Devices

§ 864.6100 Bleeding time device.

(a) Identification. A bleeding time device is a device, usually employing two spring-loaded blades, that produces two small incisions in the patient’s skin. The length of time required for the bleeding to stop is a measure of the effectiveness of the coagulation system, primarily the platelets.

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

[45 FR 60604, Sept. 12, 1980]

§ 864.6150 Capillary blood collection tube.

(a) Identification. A capillary blood collection tube is a plain or heparinized glass tube of very small diameter used to collect blood by capillary action.

(b) Classification. Class I. If the device is not intended for over-the-counter (OTC) distribution, it is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

[45 FR 60604, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989]

§ 864.6160 Manual blood cell counting device.

(a) Identification. A manual blood cell counting device is a device used to count red blood cells, white blood cells, or blood platelets.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

[45 FR 60605, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989]

§ 864.6400 Hematocrit measuring device.

(a) Identification. A hematocrit measuring device is a system consisting of instruments, tubes, racks, and a sealer and a holder. The device is used to measure the packed red cell volume in blood to determine whether the patient’s total red cell volume is normal or abnormal. Abnormal states include anemia (an abnormally low total red cell volume) and erythrocytosis (an abnormally high total red cell mass). The
packed red cell volume is produced by centrifuging a given volume of blood.

(b) Classification. Class II (performance standards).
[45 FR 60609, Sept. 12, 1980]

§ 864.6550 Occult blood test.

(a) Identification. An occult blood test is a device used to detect occult blood in urine or feces. (Occult blood is blood present in such small quantities that it can be detected only by chemical tests of suspected material, or by microscopic or spectroscopic examination.)

(b) Classification. Class II (performance standards).
[45 FR 60609, Sept. 12, 1980]

§ 864.6600 Osmotic fragility test.

(a) Identification. An osmotic fragility test is a device used to determine the resistance of red blood cells to hemolysis (destruction) in varying concentrations of hypotonic saline solutions.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.
[45 FR 60607, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989]

§ 864.6650 Platelet adhesion test.

(a) Identification. A platelet adhesion test is a device used to determine in vitro platelet function.

(b) Classification. Class II (performance standards).
[45 FR 60609, Sept. 12, 1980]

§ 864.6675 Platelet aggregometer.

(a) Identification. A platelet aggregometer is a device, used to determine changes in platelet shape and platelet aggregation following the addition of an aggregating reagent to a platelet rich plasma.

(b) Classification. Class II (performance standards).
[45 FR 60609, Sept. 12, 1980]

§ 864.6700 Erythrocyte sedimentation rate test.

(a) Identification. An erythrocyte sedimentation rate test is a device that measures the length of time required for the red cells in a blood sample to fall a specified distance or a device that measures the degree of sedimentation taking place in a given length of time. An increased rate indicates tissue damage or inflammation.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.
[45 FR 60608, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989]

Subpart H—Hematology Kits and Packages

§ 864.7040 Adenosine triphosphate release assay.

(a) Identification. An adenosine triphosphate release assay is a device that measures the release of adenosine triphosphate (ATP) from platelets following aggregation. This measurement is made on platelet-rich plasma using a photometer and a luminescent firefly extract. Simultaneous measurements of platelet aggregation and ATP release are used to evaluate platelet function disorders.

(b) Classification. Class I (general controls).
[45 FR 60609, Sept. 12, 1980]

§ 864.7060 Antithrombin III assay.

(a) Identification. An antithrombin III assay is a device that is used to determine the plasma level of antithrombin III (a substance which acts with the anticoagulant heparin to prevent coagulation). This determination is used to monitor the administration of heparin in the treatment of thrombosis. The determination may also be used in the diagnosis of thrombophilia (a congenital deficiency of antithrombin III).

(b) Classification. Class II (performance standards).
[45 FR 60609, Sept. 12, 1980]

§ 864.7100 Red blood cell enzyme assay.

(a) Identification. Red blood cell enzyme assay is a device used to measure the activity in red blood cells of clinically important enzymatic reactions and their products, such as pyruvate kinase or 2,3-diphosphoglycerate. A red blood cell enzyme assay is used to determine the enzyme defects responsible
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for a patient's hereditary hemolytic anemia.
(b) Classification. Class II (performance standards).
[45 FR 60610, Sept. 12, 1980]

§ 864.7140 Activated whole blood clotting time tests.
(a) Identification. An activated whole blood clotting time test is a device, used to monitor heparin therapy for the treatment of venous thrombosis or pulmonary embolism by measuring the coagulation time of whole blood.
(b) Classification. Class II (performance standards).
[45 FR 60611, Sept. 12, 1980]

§ 864.7250 Erythropoietin assay.
(a) Identification. A erythropoietin assay is a device that measures the concentration of erythropoietin (an enzyme that regulates the production of red blood cells) in serum or urine. This assay provides diagnostic information for the evaluation of erythrocytosis (increased total red cell mass) and anemia.
(b) Classification. Class III (premarket approval).
(c) Date PMA or notice of completion of a PDP is required.
No effective date has been established of the requirement for premarket approval. See § 864.3.

§ 864.7320 Fibrinogen/fibrin degradation products assay.
(a) Identification. A fibrinogen/fibrin degradation products assay is a device used to detect fibrinogen/fibrin degradation products and fibrin degradation products (protein fragments produced by the enzymatic action of plasmin on fibrinogen and fibrin) as an aid in detecting the presence and degree of intravascular coagulation and fibrinolysis (the dissolution of the fibrin in a blood clot) and in monitoring therapy for disseminated intravascular coagulation (nonlocalized clotting in the blood vessels).
(b) Classification. Class II (performance standards).
[45 FR 60615, Sept. 12, 1980]
§ 864.7360 Erythrocytic glucose-6-phosphate dehydrogenase assay.

(a) Identification. An erythrocytic glucose-6-phosphate dehydrogenase assay is a device used to measure the activity of the enzyme glucose-6-phosphate dehydrogenase or of glucose-6-phosphate dehydrogenase isoenzymes. The results of this assay are used in the diagnosis and treatment of nonspherocytic congenital hemolytic anemia or drug-induced hemolytic anemia associated with a glucose-6-phosphate dehydrogenase deficiency. This generic device includes assays based on fluorescence, electrophoresis, methemoglobin reduction, catalase inhibition, and ultraviolet kinetics.

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

[45 FR 60635, Sept. 12, 1980]

§ 864.7375 Glutathione reductase assay.

(a) Identification. A glutathione reductase assay is a device used to determine the activity of the enzyme glutathione reductase in serum, plasma, or erythrocytes by such techniques as fluorescence and photometry. The results of this assay are used in the diagnosis of liver disease, glutathione reductase deficiency, or riboflavin deficiency.

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

[45 FR 60636, Sept. 12, 1980]

§ 864.7400 Hemoglobin A₂ assay.

(a) Identification. A hemoglobin A₂ assay is a device used to determine the hemoglobin A₂ content of human blood. The measurement of hemoglobin A₂ is used in the diagnosis of the thalassemias (hereditary hemolytic anemias characterized by decreased synthesis of one or more types of hemoglobin polypeptide chains).

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

[45 FR 60617, Sept. 12, 1980]

§ 864.7415 Abnormal hemoglobin assay.

(a) Identification. An abnormal hemoglobin assay is a device consisting of the reagents, apparatus, instrumentation, and controls necessary to isolate and identify abnormal genetically determined hemoglobin types.

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

[45 FR 60638, Sept. 12, 1980]

§ 864.7425 Carboxyhemoglobin assay.

(a) Identification. A carboxyhemoglobin assay is a device used to determine the carboxyhemoglobin (the compound formed when hemoglobin is exposed to carbon monoxide) content of human blood as an aid in the diagnosis of carbon monoxide poisoning. This measurement may be made using methods such as spectroscopy, colorimetry, spectrophotometry, and gasometry.

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

[45 FR 60639, Sept. 12, 1980]

§ 864.7440 Electrophoretic hemoglobin analysis system.

(a) Identification. An electrophoretic hemoglobin analysis system is a device that electrophoretically separates and identifies normal and abnormal hemoglobin types as an aid in the diagnosis of anemia or erythrocytosis (increased total red cell mass) due to a hemoglobin abnormality.

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

[45 FR 60640, Sept. 12, 1980]

§ 864.7455 Fetal hemoglobin assay.

(a) Identification. A fetal hemoglobin assay is a device that is used to determine the presence and distribution of fetal hemoglobin (hemoglobin F) in red cells or to measure the amount of fetal hemoglobin present. The assay may be used to detect fetal red cells in the maternal circulation or to detect the elevated levels of fetal hemoglobin exhibited in cases of hemoglobin abnormalities such as thalassemia (a hereditary
hemolytic anemia characterized by a decreased synthesis of one or more types of hemoglobin polypeptide chains. The hemoglobin determination may be made by methods such as electrophoresis, alkali denaturation, column chromatography, or radial immunodiffusion.

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

§ 864.7470 Glycosylated hemoglobin assay.

(a) Identification. A glycosylated hemoglobin assay is a device used to measure the glycosylated hemoglobins (A1a, A1b, and A1c) in a patient’s blood by a column chromatographic procedure. Measurement of glycosylated hemoglobin is used to assess the level of control of a patient’s diabetes and to determine the proper insulin dosage for a patient. Elevated levels of glycosylated hemoglobin indicate uncontrolled diabetes in a patient.

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

[45 FR 60621, Sept. 12, 1980]

§ 864.7490 Sulfhemoglobin assay.

(a) Identification. A sulfhemoglobin assay is a device consisting of reagents, calibrators, controls, and instrumentation used to determine the sulfhemoglobin (a compound of sulfur and hemoglobin) content of human blood as an aid in the diagnosis of sulfhemoglobinemia (presence of sulfhemoglobin in the blood due to drug administration or exposure to a poison). This measurement may be made using methods such as spectrosopy, colorimetry, spectrophotometry, or gasometry.

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

[45 FR 60621, Sept. 12, 1980]

§ 864.7500 Whole blood hemoglobin assays.

(a) Identification. A whole blood hemoglobin assay is a device consisting of reagents, calibrators, controls, or photometric or spectrophotometric instrumentation used to measure the hemoglobin content of whole blood for the detection of anemia. This generic device category does not include automated hemoglobin systems.

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

[45 FR 60622, Sept. 12, 1980]

§ 864.7525 Heparin assay.

(a) Identification. A heparin assay is a device used to determine the level of the anticoagulant heparin in the patient’s circulation. These assays are quantitative clotting time procedures using the effect of heparin on activated coagulation factor X (Stuart factor) or procedures based on the neutralization of heparin by protamine sulfate (a protein that neutralizes heparin).

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

[45 FR 60623, Sept. 12, 1980]

§ 864.7660 Leukocyte alkaline phosphatase test.

(a) Identification. A leukocyte alkaline phosphatase test is a device used to identify the enzyme leukocyte alkaline phosphatase in neutrophilic granulocytes (granular leukocytes stainable by neutral dyes). The cytochemical identification of alkaline phosphatase depends on the formation of blue granules in cells containing alkaline phosphatase. The results of this test are used to differentiate chronic granulocytic leukemia (a malignant disease characterized by excessive overgrowth of granulocytes in the bone marrow) and reactions that resemble true leukemia, such as those occurring in severe infections and polycythemia (increased total red cell mass).

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.


§ 864.7675 Leukocyte peroxidase test.

(a) Identification. A leukocyte peroxidase test is a device used to distinguish certain myeloid cells derived from the bone marrow, i.e., neutrophils, eosinophils, and monocytes, from lymphoid cells of the lymphatic system and erythroid cells of the red blood cell series on the basis of their peroxidase activity as evidenced by staining. The
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results of this test are used in the differential diagnosis of the leukemias.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

§ 864.7695 Platelet factor 4 radioimmunoassay.

(a) Identification. A platelet factor 4 radioimmunoassay is a device used to measure the level of platelet factor 4, a protein released during platelet activation by radioimmunoassay. This device measures platelet activation, which may indicate a coagulation disorder, such as myocardial infarction or coronary artery disease.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

§ 864.7720 Prothrombin consumption test.

(a) Identification. A prothrombin consumption test is a device that measures the patient’s capacity to generate thromboplastin in the coagulation process. The test also is an indirect indicator of qualitative or quantitative platelet abnormalities. It is a screening test for thrombocytopenia (decreased number of blood platelets) and hemophilia A and B.

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

§ 864.7780 Sickle cell test.

(a) Identification. A sickle cell test is a device used to determine the sickle cell hemoglobin content of human blood to detect sickle cell trait or sickle cell diseases.

(b) Classification. Class II (performance standards).
[45 FR 60627, Sept. 12, 1980]

§ 864.7900 Thromboplastin generation test.

(a) Identification. The prothrombin-proconvertin test and thrombostest are devices used in the regulation of coumarin therapy (administration of a coumarin anticoagulant such as sodium warfarin in the treatment of venous thrombosis and pulmonary embolism) and as a diagnostic test in conjunction with, or in place of, the Quick prothrombin time test to detect coagulation disorders.

(b) Classification. Class II (performance standards).
[45 FR 60626, Sept. 12, 1980]

§ 864.7925 Partial thromboplastin time tests.

(a) Identification. A partial thromboplastin time test is a device used for