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such as hematoxylin and eosin. Examples of class I IHC's are differentiation markers that are used as adjunctive tests to subclassify tumors, such as keratin.

(2) Class II (special control, guidance document: "FDA Guidance for Submission of Immunohistochemistry Applications to the FDA," Center for Devices and Radiologic Health, 1998). These IHC's are intended for the detection and/or measurement of certain target analytes in order to provide prognostic or predictive data that are not directly confirmed by routine histopathologic internal and external control specimens. These IHC's provide the pathologist with information that is ordinarily reported as independent diagnostic information to the ordering clinician, and the claims associated with these data are widely accepted and supported by valid scientific evidence. Examples of class II IHC's are those intended for semiquantitative measurement of an analyte, such as hormone receptors in breast cancer.

(3) Class III (premarket approval). IHC's intended for any use not described in paragraphs (b)(1) or (b)(2) of this section.

(c) *Date of PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the Federal Food, Drug, and Cosmetic Act is required for any device described in paragraph (b)(3) of this section before this device may be commercially distributed. See § 864.3.

[63 FR 30142, June 3, 1998]

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

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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, disks, 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, and § 820.198, with respect to complaint files.

[45 FR 60584, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989]

§ 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.