Food and Drug Administration, HHS

§ 866.2450 Supplement for culture media.

(a) Identification. A supplement for culture media is a device, such as a vitamin or sugar mixture, that is added to a solid or liquid basal culture medium to produce a desired formulation and that is intended for medical purposes to enhance the growth of fastidious microorganisms (those having complex nutritional requirements). This device aids in the diagnosis of diseases caused by pathogenic microorganisms.

(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 §866.9.

§ 866.2440 Automated medium dispensing and stacking device.

(a) Identification. An automated medium dispensing and stacking device is a device intended for medical purposes to dispense a microbiological culture medium into petri dishes and then mechanically stack the petri dishes.

(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 §866.9. The device is also exempt from the 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.

§ 866.2430 Transport culture medium.

(a) Identification. A transport culture medium is a device that consists of a semisolid, usually non-nutrient, medium that maintains the viability of suspected pathogens contained in patient specimens while in transit from the specimen collection area to the laboratory. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

(b) Classification. Class I (general controls).

§ 866.2410 Culture medium for pathogenic Neisseria spp.

(a) Identification. A culture medium for pathogenic Neisseria spp. is a device that consists primarily of liquid or solid biological materials used to cultivate and identify pathogenic Neisseria spp. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus Neisseria, such as epidemic cerebrospinal meningitis, other meningococcal disease, and gonorrhea, and also provides epidemiological information on these microorganisms.

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

§ 866.2420 Oxidase screening test for gonorrhea.

(a) Identification. An oxidase screening test for gonorrhea is an in vitro device that consists of the articles intended to identify by chemical reaction, cytochrome oxidase, an oxidizing enzyme that is associated with certain bacteria including Neisseria gonorrhoeae. A sample of a male’s urethral discharge is obtained on a swab which is placed into a wetting agent containing an ingredient that will react with cytochrome oxidase. When cytochrome oxidase is present, the swab turns a dark purple color within 3 minutes. Because it is unlikely that cytochrome oxidase-positive organisms other than Neisseria gonorrhoeae are present in the urethral discharge of males, the identification of cytochrome oxidase with this device indicates presumptive infection of the patient with the causative agent of gonorrhea.

(b) Classification. Class III (premarket approval) (transitional device).

(c) Date PMA or notice of completion of a PDP is required. As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See §866.3.

§ 866.2425 Oxidase screening test for Neisseria meningitidis.

(a) Identification. An oxidase screening test for Neisseria meningitidis is an in vitro device that consists of the articles intended to identify by chemical reaction, cytochrome oxidase, an oxidizing enzyme that is associated with certain bacteria including Neisseria meningitidis. A sample of a patient’s specimen, such as meningococcal meningitis, is obtained on a swab which is placed into a wetting agent containing an ingredient that will react with cytochrome oxidase. When cytochrome oxidase is present, the swab turns a dark purple color within 3 minutes. Because it is unlikely that cytochrome oxidase-positive organisms other than Neisseria meningitidis are present in the specimen, the identification of cytochrome oxidase with this device indicates presumptive infection of the patient with the causative agent of meningococcal meningitis.

(b) Classification. Class III (premarket approval) (transitional device).

§ 866.2390 Transport culture medium.

(a) Identification. A transport culture medium is a device that consists of a semisolid, usually non-nutrient, medium that maintains the viability of suspected pathogens contained in patient specimens while in transit from the specimen collection area to the laboratory. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

(b) Classification. Class I (general controls).

§ 866.2400 Supplement for culture media.

(a) Identification. A supplement for culture media is a device, such as a vitamin or sugar mixture, that is added to a solid or liquid basal culture medium to produce a desired formulation and that is intended for medical purposes to enhance the growth of fastidious microorganisms (those having complex nutritional requirements). This device aids in the diagnosis of diseases caused by pathogenic microorganisms.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in

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