

§ 866.2450

requirements concerning records, and § 820.198, with respect to complaint files.

[47 FR 50823, Nov. 9, 1982, as amended at 66 FR 38791, July 25, 2001]

§ 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.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25046, June 12, 1989; 66 FR 38791, July 25, 2001]

§ 866.2480 Quality control kit for culture media.

(a) *Identification.* A quality control kit for culture media is a device that consists of paper discs (or other suitable materials), each impregnated with a specified, freeze-dried, viable microorganism, intended for medical purposes to determine if a given culture medium is able to support the growth of that microorganism. 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). 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.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25046, June 12, 1989; 66 FR 38791, July 25, 2001]

§ 866.2500 Microtiter diluting and dispensing device.

(a) *Identification.* A microtiter diluting and dispensing device is a mechanical device intended for medical pur-

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poses to dispense or serially dilute very small quantities of biological or chemical reagents for use in various diagnostic procedures.

(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.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25046, June 12, 1989; 66 FR 38791, July 25, 2001]

§ 866.2540 Microbiological incubator.

(a) *Identification.* A microbiological incubator is a device with various chambers or water-filled compartments in which controlled environmental conditions, particularly temperature, are maintained. It is intended for medical purposes to cultivate microorganisms and aid in the diagnosis of disease.

(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.

[47 FR 50823, Nov. 9, 1982, as amended at 66 FR 38791, July 25, 2001]

§ 866.2560 Microbial growth monitor.

(a) *Identification.* A microbial growth monitor is a device intended for medical purposes that measures the concentration of bacteria suspended in a liquid medium by measuring changes in light scattering properties, optical density, electrical impedance, or by making direct bacterial counts. The device aids in the diagnosis of disease caused by pathogenic microorganisms.

(b) *Classification.* Class I. With the exception of automated blood culturing system devices that are used in testing for bacteria, fungi, and other microorganisms in blood and other normally sterile body fluids, this device is exempt from the premarket notification

procedures in subpart E of part 807 of this chapter.

[47 FR 50823, Nov. 9, 1982, as amended at 60 FR 38482, July 27, 1995]

§ 866.2580 Gas-generating device.

(a) *Identification.* A gas-generating device is a device intended for medical purposes that produces predetermined amounts of selected gases to be used in a closed chamber in order to establish suitable atmospheric conditions for cultivation of microorganisms with special atmospheric requirements. The device aids in the diagnosis of disease.

(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.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25046, June 12, 1989; 66 FR 38791, July 25, 2001]

§ 866.2600 Wood's fluorescent lamp.

(a) *Identification.* A Wood's fluorescent lamp is a device intended for medical purposes to detect fluorescent materials (e.g., fluorescein pigment produced by certain microorganisms) as an aid in the identification of these microorganisms. The device aids in the diagnosis of disease.

(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.

[47 FR 50823, Nov. 9, 1982, as amended at 66 FR 38791, July 25, 2001]

§ 866.2660 Microorganism differentiation and identification device.

(a) *Identification.* A microorganism differentiation and identification device is a device intended for medical purposes that consists of one or more components, such as differential culture media, biochemical reagents, and paper discs or paper strips impregnated

with test reagents, that are usually contained in individual compartments and used to differentiate and identify selected microorganisms. The device aids in the diagnosis of disease.

(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 § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2311, Jan. 14, 2000]

§ 866.2850 Automated zone reader.

(a) *Identification.* An automated zone reader is a mechanical device intended for medical purposes to measure zone diameters of microbial growth inhibition (or exhibition), such as those observed on the surface of certain culture media used in disc-agar diffusion antimicrobial susceptibility tests. The device aids in decisionmaking respecting the treatment of disease.

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

§ 866.2900 Microbiological specimen collection and transport device.

(a) *Identification.* A microbiological specimen collection and transport device is a specimen collecting chamber intended for medical purposes to preserve the viability or integrity of microorganisms in specimens during storage of specimens after their collection and during their transport from the collecting area to the laboratory. The device may be labeled or otherwise represented as sterile. The device aids in the diagnosis of disease caused by pathogenic microorganisms.

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

Subpart D—Serological Reagents

§ 866.3010 *Acinetobacter calcoaceticus* serological reagents.

(a) *Identification.* *Acinetobacter calcoaceticus* serological reagents are devices that consist of *Acinetobacter calcoaceticus* antigens and antisera used to identify this bacterium from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by the bacterium *Acinetobacter calcoaceticus*