§ 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 §866.9.

§ 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.

§ 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.

§ 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...
and provides epidemiological information on disease caused by this microorganism. This organism becomes pathogenic in patients with burns or with immunologic deficiency, and infection can result in sepsis (blood poisoning).

(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.

§866.3020 Adenovirus serological reagents.

(a) Identification. Adenovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to adenovirus in serum. Additionally, some of these reagents consist of adenovirus antisera conjugated with a fluorescent dye and are used to identify adenoviruses directly from clinical specimens. The identification aids in the diagnosis of disease caused by adenoviruses and provides epidemiological information on these diseases. Adenovirus infections may cause pharyngitis (inflammation of the throat), acute respiratory diseases, and certain external diseases of the eye (e.g., conjunctivitis).

(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.

§866.3035 Arizona spp. serological reagents.

(a) Identification. Arizona spp. serological reagents are devices that consist of antisera and antigens used to identify Arizona spp. in cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus Arizona and provides epidemiological information on diseases caused by these microorganisms. Arizona spp. can cause gastroenteritis (food poisoning) and sepsis (blood poisoning).

(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.

§866.3040 Aspergillus spp. serological reagents.

(a) Identification. Aspergillus spp. serological reagents are devices that consist of antigens and antisera used in various serological tests to identify antibodies to Aspergillus spp. in serum. The identification aids in the diagnosis of aspergillosis caused by fungi belonging to the genus Aspergillus. Aspergillosis is a disease marked by inflammatory granulomatous (tumor-like) lesions in the skin, ear, eyeball cavity, nasal sinuses, lungs, and occasionally the bones.

(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.

§866.3050 Beta-glucan serological assays.

(a) Identification. Beta-glucan serological assays are devices that consist of antigens or proteases used in serological assays. The device is intended for use for the presumptive diagnosis of fungal infection. The assay is indicated for use in patients with symptoms of, or medical conditions predisposing the patient to invasive fungal infection. The device can be used as an aid in the diagnosis of deep seated mycoses and fungemias.

(b) Classification. Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Serological Assays for the Detection of Beta-Glucan.” See §866.1(e) for the availability of this guidance document.