

§ 866.3035

21 CFR Ch. I (4–1–12 Edition)

§ 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.

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

§ 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 § 866.9.

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

§ 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.

[69 FR 56936, Sept. 23, 2004]

§ 866.3060 *Blastomyces dermatitidis* serological reagents.

(a) *Identification.* *Blastomyces dermatitidis* serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Blastomyces dermatitidis* in serum. The identification aids in the diagnosis of blastomycosis caused by the fungus *Blastomyces dermatitidis*. Blastomycosis is a chronic granulomatous (tumor-like) disease, which may be limited to the skin or lung or may be widely disseminated in the body resulting in lesions of the bones, liver, spleen, and kidneys.

(b) *Classification.* Class II (special 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 63 FR 59226, Nov. 3, 1998]

§ 866.3065 *Bordetella* spp. serological reagents.

(a) *Identification.* *Bordetella* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye, used in serological tests to identify *Bordetella* spp. from cultured isolates or directly from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Bordetella* and provides epidemiological information on these diseases. *Bordetella* spp. cause whooping cough (*Bordetella pertussis*) and other similarly contagious and acute respiratory infections characterized by pneumonitis (inflammation of the lungs).

(b) *Classification.* Class I (general controls). The device is exempt from the