§ 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 §866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 63 FR 59226, Nov. 3, 1998]

§ 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 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]