specimens. The identification aids in the diagnosis of diseases caused by this bacterium belonging to the genus *Escherichia*, and provides epidemiological information on diseases caused by this microorganism. Although *Escherichia coli* constitutes the greater part of the microorganisms found in the intestinal tract in humans and is usually non-pathogenic, those strains which are pathogenic may cause urinary tract infections or epidemic diarrheal disease, especially in children.

(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]

§ 866.3270 *Flavobacterium* spp. serological reagents.

(a) Identification. *Flavobacterium* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Flavobacterium* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Flavobacterium* and provides epidemiological information on diseases caused by these microorganisms. Most members of this genus are found in soil and water and, under certain conditions, may become pathogenic to humans. *Flavobacterium meningosepticum* is highly virulent for the newborn, in whom it may cause epidemics of septicemia (blood poisoning) and meningitis (inflammation of the membranes of the brain) and is usually attributable to contaminated hospital equipment.

(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 63 FR 59226, Nov. 3, 1998]

§ 866.3290 Gonococcal antibody test (GAT).

(a) Identification. A gonococcal antibody test (GAT) is an in vitro device that consists of the reagents intended to identify by immunochromel techniques, such as latex agglutination, indirect fluorescent antibody, or radioimmunoassay, antibodies to *Neisseria gonorrhoeae* in sera of symptomatic females at low risk of infection. Identification of antibodies with this device may indicate past or present infection of the patient with *Neisseria gonorrhoeae*.

(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.

[47 FR 50823, Nov. 9, 1982, as amended at 52 FR 17734, May 11, 1987]