§ 866.3470
is commonly transmitted to humans by
a bite from a rabid animal.
(b) Classification. Class II (performance
standards).

§ 866.3470 Reovirus serological re-
agents.
(a) Identification. Reovirus serological
reagents are devices that consist of
antigens and antisera used in sero-
logical tests to identify antibodies to
reovirus in serum. The identification
aids in the diagnosis of reovirus infec-
tions and provides epidemiological in-
formation on diseases caused by these
viruses. Reoviruses are thought to
cause only mild respiratory and gastro-
intestinal illnesses.
(b) Classification. Class I (general con-
trols). 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 25047, June 12, 1989; 66 FR 38792, July 25,
2001]

§ 866.3480 Respiratory syncytial virus
serological reagents.
(a) Identification. Respiratory
syncytial virus serological reagents are
deVICES that consist of antigens and
antisera used in serological tests to
identify antibodies to respiratory
syncytial virus in serum. Additionally,
some of these reagents consist of respi-
ratory syncytial virus antisera con-
jugated with a fluorescent dye
(immunofluorescent reagents) and used
to identify respiratory syncytial vi-
ruses from clinical specimens or from
tissue culture isolates derived from
clinical specimens. The identification
aids in the diagnosis of respiratory
syncytial virus infections and provides
epidemiological information on dis-
eases caused by these viruses. Respir-
atory syncytial viruses cause a
number of respiratory tract infections,
including the common cold, pharyn-
gitis, and infantile bronchopneumonia.
(b) Classification. Class I (general con-
trols). 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 2312, Jan. 14, 2000]