Food and Drug Administration, HHS

§ 866.5180 Fecal calprotectin
immunological test system.

(a) Identification. A fecal calprotectin
immunological test system is an in
vitro diagnostic device that consists of
reagents used to measure by immunochemical
techniques fecal calprotectin in human stool
specimens. The device is intended for in
vitro diagnostic use as an aid in the
diagnosis of inflammatory bowel diseases
(IBD), specifically Crohn’s disease and
carcinoid syndrome, and as an aid in dif-
ferentiation of IBD from irritable
bowel syndrome.

(b) Classification. Class II (special
controls). The special control for these
devices is FDA’s guidance document
entitled “Class II Special Controls
Guidance Document: Fecal

§ 866.5160 Beta-globulin immunological
test system.

(a) Identification. A beta-globulin
immunological test system is a device
that consists of reagents used to measure by immunochemical
techniques beta globulins (serum protein) in serum
and other body fluids. Beta-globulin
proteins include beta-lipoprotein, transferrin, glycoproteins, and com-
plement, and are rarely associated with
specific pathologic disorders.

(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.

§ 866.5170 Breast milk immunological
test system.

(a) Identification. A breast milk
immunological test system is a device
that consists of the reagents used to
measure by immunochemical tech-
niques the breast milk proteins.

(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.