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 ulcerative colitis, and as an aid in differentiation 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...