Subpart G—Manual Hematology Devices

§ 864.6100 Bleeding time device.
(a) Identification. A bleeding time device is a device, usually employing two spring-loaded blades, that produces two small incisions in the patient’s skin. The length of time required for the bleeding to stop is a measure of the effectiveness of the coagulation system, primarily the platelets.

(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 §864.9.


§ 864.6150 Capillary blood collection tube.
(a) Identification. A capillary blood collection tube is a plain or heparinized glass tube of very small diameter used to collect blood by capillary action.

(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 §864.9.


§ 864.6160 Manual blood cell counting device.
(a) Identification. A manual blood cell counting device is a device used to count red blood cells, white blood cells, or blood platelets.

(b) Classification. Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §864.9.


§ 864.6400 Hematocrit measuring device.
(a) Identification. A hematocrit measuring device is a system consisting of instruments, tubes, racks, and a sealer and a holder. The device is used to measure the packed red cell volume in