§ 864.4400 Enzyme preparations.

(a) Identification. Enzyme preparations are products that are used in the histopathology laboratory for the following purposes:

(1) To disaggregate tissues and cells already in established cultures for preparation into subsequent cultures (e.g., trypsin);

(2) To disaggregate fluid specimens for cytological examination (e.g., papain for gastric lavage or trypsin for sputum liquefaction);

(3) To aid in the selective staining of tissue specimens (e.g., diastase for glycogen determination).

(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.

Subpart F—Automated and Semi-Automated Hematology Devices

§ 864.5200 Automated cell counter.

(a) Identification. An automated cell counter is a fully-automated or semi-automated device used to count red blood cells, white blood cells, or blood platelets using a sample of the patient’s peripheral blood (blood circulating in one of the body’s extremities, donor screening for conditions for which FDA has recommended or required testing in order to safeguard the blood supply or establish the safe use of blood and blood products (e.g., tests for hepatitis or tests for identifying blood groups).

(c) Date of 510(k), or date of PMA or notice of completion of a product development protocol is required. (1) Preamendments ASR’s: No effective date has been established for the requirement for premarket approval for the device described in paragraph (b)(3) of this section. See §864.3.

(2) For postamendments ASR’s: November 23, 1998.

(d) Restrictions. Restrictions on the sale, distribution and use of ASR’s are set forth in §809.30 of this chapter.

such as the arm). These devices may also measure hemoglobin or hematocrit and may also calculate or measure one or more of the red cell indices (the erythrocyte mean corpuscular volume, the mean corpuscular hemoglobin, or the mean corpuscular hemoglobin concentration). These devices may use either an electronic particle counting method or an optical counting method.

(b) **Classification.** Class II (performance standards).

[45 FR 60593, Sept. 12, 1980]

§ 864.5220 Automated differential cell counter.

(a) **Identification.** An automated differential cell counter is a device used to identify one or more of the formed elements of the blood. The device may also have the capability to flag, count, or classify immature or abnormal hematopoietic cells of the blood, bone marrow, or other body fluids. These devices may combine an electronic particle counting method, optical method, or a flow cytometric method utilizing monoclonal CD (cluster designation) markers. The device includes accessory CD markers.

(b) **Classification.** Class II (special controls). The special control for this device is the FDA document entitled “Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA.”

[67 FR 1607, Jan. 14, 2002]

§ 864.5240 Automated blood cell diluting apparatus.

(a) **Identification.** An automated blood cell diluting apparatus is a fully automated or semi-automated device used to make appropriate dilutions of a blood sample for further testing.

(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 §864.9.


§ 864.5260 Automated cell-locating device.

(a) **Identification.** An automated cell-locating device is a device used to locate blood cells on a peripheral blood smear, allowing the operator to identify and classify each cell according to type. (Peripheral blood is blood circulating in one of the body’s extremities, such as the arm.)

(b) **Classification.** Class II (performance standards).

[45 FR 60597, Sept. 12, 1980]

§ 864.5300 Red cell indices device.

(a) **Identification.** A red cell indices device, usually part of a larger system, calculates or directly measures the erythrocyte mean corpuscular volume (MCV), the mean corpuscular hemoglobin (MCH), and the mean corpuscular hemoglobin concentration (MCHC). The red cell indices are used for the differential diagnosis of anemias.

(b) **Classification.** Class II (performance standards).

[45 FR 60597, Sept. 12, 1980]

§ 864.5350 Microsedimentation centrifuge.

(a) **Identification.** A microsedimentation centrifuge is a device used to sediment red cells for the microsedimentation rate test.

(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.


§ 864.5400 Coagulation instrument.

(a) **Identification.** A coagulation instrument is an automated or semi-automated device used to determine the onset of clot formation for in vitro coagulation studies.

(b) **Classification.** Class II (performance standards).

[45 FR 60598, Sept. 12, 1980]