§ 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, 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).