Food and Drug Administration, HHS

§ 864.4020

Analyte specific reagents.

(a) Identification. Analyte specific reagents (ASR's) are antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid sequences, and similar reagents which, through specific binding or chemical reaction with substances in a specimen, are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens. ASR's that otherwise fall within this definition are not within the scope of subpart E of this chapter when they are sold to:

(1) In vitro diagnostic manufacturers; or

(2) Organizations that use the reagents to make tests for purposes other than providing diagnostic information to patients and practitioners, e.g., forensic, academic, research, and other nonclinical laboratories.

(b) Classification. (1) Class I (general controls). Except as described in paragraphs (b)(2) and (b)(3) of this section, these devices are exempt from the premarket notification requirements in part 807, subpart E of this chapter.

(2) Class II (special controls/guidance documents), when the analyte is used in blood banking tests that have been classified as class II devices (e.g., certain cytomegalovirus serological and treponema pallidum nontreponemal test reagents). Guidance Documents:


5. The Center for Biologics Evaluation and Research, FDA, “Points to Consider in the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Antibodies to the Human Immunodeficiency Virus, Type I” (54 FR 48943, November 28, 1989).

(3) Class III (premarket approval), when:

(i) The analyte is intended as a component in a test intended for use in the diagnosis of a contagious condition that is highly likely to result in a fatal outcome and prompt, accurate diagnosis offers the opportunity to mitigate the public health impact of the condition (e.g., human immunodeficiency virus (HIV/AIDS)); or

(ii) The analyte is intended as a component in a test intended for use in 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).
§ 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 established for culture 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 glycoprotein determination).

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

[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). The device is exempt from the premarket notification procedures in subpart E 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.)