§ 864.9245 Automated blood cell separator.

(a) Identification. An automated blood cell separator is a device that uses a centrifugal or filtration separation principle to automatically withdraw whole blood from a donor, separate the whole blood into blood components, collect one or more of the blood components, and return to the donor the remainder of the whole blood and blood components. The automated blood cell separator device is intended for routine collection of blood and blood components for transfusion or further manufacturing use.

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

[45 FR 60647, Sept. 12, 1980]

§ 864.9275 Blood bank centrifuge for in vitro diagnostic use.

(a) Identification. A blood bank centrifuge for in vitro diagnostic use is a device used only to separate blood cells for further diagnostic testing.

(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.