food and drug administration, hhs

§ 864.9225 Cell-freezing apparatus and reagents for in vitro diagnostic use.

(a) Identification. Cell-freezing apparatus and reagents for in vitro diagnostic use are devices used to freeze

(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.


§ 864.9195 Blood mixing devices and blood weighing devices.

(a) Identification. A blood mixing device is a device intended for medical purposes that is used to mix blood or blood components by agitation. A blood weighing device is a device intended for medical purposes that is used to weigh blood or blood components as they are collected.

(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.


§ 864.9205 Blood and plasma warming device.

(a) Nonelectromagnetic blood or plasma warming device—(1) Identification. A nonelectromagnetic blood and plasma warming device is a device that warms blood or plasma, by means other than electromagnetic radiation, prior to administration.

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

(b) Electromagnetic blood and plasma warming device—(1) Identification. An electromagnetic blood and plasma warming device is a device that employs electromagnetic radiation (radiowaves or microwaves) to warm a bag or bottle of blood or plasma prior to administration.

(2) Classification. Class III (premarket approval).

(c) Date PMA or notice of completion of a PDP is required. No effective date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See §864.3.