§ 864.9700 Blood storage refrigerator and blood storage freezer.

(a) *Identification.* A blood storage refrigerator and a blood storage freezer are devices intended for medical purposes that are used to preserve blood and blood products by storing them at cold or freezing temperatures.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60650, Sept. 12, 1980, as amended at 63 FR 59226, Nov. 3, 1998]

§ 864.9750 Heat-sealing device.

(a) *Identification.* A heat-sealing device is a device intended for medical purposes that uses heat to seal plastic bags containing blood or blood components.

(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.

[45 FR 60650, Sept. 12, 1980, as amended at 65 FR 2311, Jan. 14, 2000]

§ 864.9875 Transfer set.

(a) *Identification.* A transfer set is a device intended for medical purposes that consists of a piece of tubing with suitable adaptors used to transfer blood or plasma from one container to another.

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

[45 FR 60651, Sept. 12, 1980]

Subpart K—Products Used In Establishments That Manufacture Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)

§ 864.9900 Cord blood processing system and storage container.

(a) *Identification.* A cord blood processing system and storage container is a device intended for use in the processing and the storage of cord blood. This device is a functionally closed processing system that includes containers, other soft goods, and a centrifugation system for cord blood concentration, and a final container for the cryopreservation and the storage of a cord blood product.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Cord Blood Processing System and Storage Container.'' For the availability of this guidance document, see § 864.1(d).

[72 FR 4638, Feb. 1, 2007]

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

Subpart A—General Provisions

Subpart B—Diagnostic Devices

Subpart C—Microbiology Devices